Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0999860	09/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
Susan E Dozier Md Pa	8240 North Mopac Expressway Suite 355, Austin, 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 laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended. Standard level deficiencies were cited.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, reagent log, interview, and presurvey paperwork, the laboratory failed to retain the chemical name and concentration (if applicable), manufacturer, lot number, expiration date, received date, and open date of the chemicals and stains used in the laboratory for Mohs testing for two of two years reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Laboratory Procedure Manual Histopathology- Mohs Surgery, approved 08/31/1999, under Procedure and Form 10: Histopathology - Mohs Surgery Reagent Storage, Use, and Handling stated, "Do not use reagent after expiration date." B. Review of the reagent log from 09/26/2022 - 09/25/2024 was missing the documentation of the chemicals and stains (Bluing, 100% Reagent Alcohol, Xylene Substitute, etc.) other than for Hematoxylin and Eosin. C. Interview with the histotechnologist on September 25, 2024 at 1100 hours in the laboratory confirmed the findings D. Review of the CMS Form 116 showed an estimated annual volume of 2821 blocks.
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 the laboratory's policies and procedures, accuracy assessments, pre-survey paperwork, and interview, the laboratory failed to provide documentation of twice a year accuracy assessments of Mohs testing for one of two years reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Quality Assurance Manual (approved 08/31/1999), under Comparison of Test Results stated, "... Any test performed in the laboratory for which proficiency testing is not available will be verified at least twice a year, and the results will be reviewed by the Laboratory Director." B. Review of the accuracy assessments from 2022 and 2023 showed one accuracy assessment in 2022. C. Review of the CMS Form 116 showed an estimated annual volume of 2821 blocks. D. Interview with the histotechnologist on September 25, 2024 at 1025 hours in the laboratory confirmed the findings.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, slides, and interview, the laboratory failed to identify and correct slides for one of 11 cases reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Histopathology Mohs Surgery, approved 08/31/1999, Specimen Handling, Storage, Transport, Preservation, and Identification stated, "Slides are labeled with number, patient's last name, stage number and piece number." B. Review of slides showed one case, SD23-394, had two out of four slides labeled with the wrong Case number: SD23-392. C. Interview with the histotechnologist on September 25, 2024 at 1215 hours stated the laboratory had identified and corrected mislabeled slides, but must not have reviewed this box.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory policy and procedure, observation, and interview, the laboratory failed to define the frequency of cleaning the vent on two of two Advantik QS12 cryostats. Findings follow. A. Review of the Advantik QS12 Cryostat Instruction Manual, UM-QS12-0001- Rev 001, at Cleaning and Care under Cleaning the Cooling Vent stated, "Open the cleaning door with a coin

	on the left and right side. Remove the dust from the cooling grill/vent by means of a commercially available vacuum cleaner. Note: Carry out this cleaning in regular intervals, thus extending the lifetime of the compressor." B. Review of the laboratory's policies and procedures did not address the frequency of the cleaning of the vent. C. On September 25, 2024 at 1145 hours surveyor observed a layer of dust /lint over the vent of both cryostats. D. Interview with the histotechnologist on September 25, 2024 at 1145 hours stated she had never cleaned the cryostat vent.
D6127	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedures, pre-survey paperwork, laboratory records, and interview, the technical supervisor failed to evaluate the competency at least semi-annually during the first year the individual tested patient specimens for one of one new hire that performed Mohs testing. Findings follow. A. Review of the laboratory's policy and procedure titled Quality Assurance Manual (approved 08/31/1999), under Personnel Assessment stated, "If the laboratory has any employees, the Laboratory Director will use personal observation to perform an ongoing evaluation of all employees of the laboratory to ensure competency in job performance." There are 6 components of a competency evaluation, and only one, direct observation, is mentioned in the policy. Frequency of competency evaluations was not included in the policy. B. Review of the pre-survey paperwork titled Laboratory Personnel showed testing personnel #2 (as listed on the CMS form 209), began Mohs testing on 10/06/2022 (elapsed time: 1 year, 11 months, 19 days). C. Review of the laboratory records showed no semi-annual competency evaluations performed. A competency evaluation was requested on 9/25/2024 at 0945 hours but not provided. D. Interview with the histotechnologist on September 25, 2024 at 0945 hours confirmed they had not performed semi annual competency evaluations.