Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1018671	02/22/2023
Name of Provider or Supplier	**Street Address, City, State**	
Rene' Koppel, Md, A Professional Medical Corp	3640 Houma Boulevard, Metairie, LA	

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 Certification survey was performed on February 22, 2023 at Rene' Koppel, MD, A Professional Medical Corp, CLIA ID # 19D1018671. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, verification of accuracy of test performance logs, and interview with personnel, the laboratory failed to follow their established policy for verification of accuracy of test performance for 2021 and 2022 for Histopathology. Findings: 1. Review of the laboratory's "Proficiency Testing" policy revealed "Semi-annually, the doctor (Laboratory Director) will send two randomly-selected cases containing the original slides for micrographic examination by a Board-Certified Dermatopathologist." 2. Review of the laboratory's logs for verification of accuracy of test performance labeled "Proficiency Testing" revealed the laboratory did not submit two cases semi-annually for review per laboratory policy for the following: November 26, 2021: one case reviewed May 13, 2022: one case reviewed December 30, 2022: one case reviewed 3. In interview on February 22, 2023 at 11:32 am, the Laboratory Director stated two cases should be sent for review semi-annually (total of four cases a year). The Laboratory Director confirmed the laboratory's policy was not followed.
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: Based on observation, record review and interview with personnel, the laboratory failed to monitor cryostat temperature, room temperature, and humidity where Histopathology is performed per manufacturer requirements on three (3) of thirty-nine (39) days of testing in 2022. Findings: 1. Observation by surveyors during the laboratory tour on February 22, 2023 revealed the laboratory utilizes the Leica Cryostat. 2. Review of the laboratory's 2022 log for monitoring the cryostat temperature revealed the laboratory failed to monitor the cryostat temperature on the following date of patient testing: July 15, 2022 3. Review of the laboratory's 2022 log for monitoring room temperature and humidity, the laboratory failed to monitor the room temperature and humidity on the following dates of patient testing: May 6, 2022 August 26, 2022 4. In interview on February 22 at 11:03 am, Histotech confirmed the laboratory did not document the cryostat temperature, room temperature, or humidity where the cryostat is located on the dates listed above.
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 review of the laboratory's CMS-209 form, quality control records, policies, test menu, and interview with personnel, the laboratory failed to ensure the testing personnel signed the quality control logs indicating his performance of the assessment of stain quality for Hematoxylin and Eosin (H&E) staining in 2022. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the Laboratory Director serves as the Testing Personnel for Mohs (Histopathology). 2. Review of the laboratory's "Frozen Section Procedure" revealed "Stain as usual in the Hematoxylin and Eosin procedure and coverslip. The surgeon will then read the slide and generate a pathology report." 3. Review of the laboratory's "Quality Control Staining" log for 2022 revealed the laboratory had documentation of the acceptability of the stain quality; however, the Laboratory Director's signature was not included indicating his performance of the assessment. 4. In interview on February 22, 2023 at 10:09 am, the Histotech confirmed the Laboratory Director did not sign the quality control logs indicating his review/acceptability of the stain quality for Mohs. 5. Review of the laboratory's test menu revealed the laboratory performs 100 Mohs tests annually.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that laboratory personnel performed the test methods as required. Findings: 1. The laboratory failed to monitor cryostat temperature, room temperature, and humidity where Histopathology is performed per manufacturer requirements on three (3) of thirty-nine (39) days of testing in 2022. Refer to D5413. 36645 2. The laboratory failed to ensure the testing personnel signed the quality control logs indicating his performance of the assessment of stain quality for Hematoxylin and Eosin (H&E) staining in 2022. D5609.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5401.