Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1003288	02/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Jackson Clinic Pa, The	87-B Murray Guard Drive, Jackson, TN	

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
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 observation of the laboratory, review of patient records, document request and staff interview, the laboratory failed to verify the accuracy of its' histopathology procedures twice a year in 2022 and 2023 with approximately 200 patient Mohs cases performed since testing began on 10/10/22. The findings include: 1. Observation of the laboratory on 02/13/23 at 8:30 am revealed equipment and stains in use for preparing tissue removed during Mohs surgery for histopathology procedures. 2. Review of patient records revealed the first Mohs case was performed on 10/10/22 (Patient case number JC22-001), with approximately 200 patient Mohs cases performed since testing began. 3. Request on 02/13/23 at 11am for verification of accuracy records for the laboratory's histopathology procedures revealed no records were available from 2022 or 2023. 4. Interview with the lab director on 02/13/23 at 12: 15 pm confirmed the laboratory failed to verify the accuracy of its' histopathology procedures twice a year in 2022 and 2023 with the first patient tested on 10/10/22.
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 procedure manual, the Mohs procedure manual, patient Mohs cases, document request, and staff interview the laboratory failed to follow its' own policy for monitoring of preanalytic systems in 2022 and 2023. The findings include: 1. Review of the laboratory procedure manual in section D. Laboratory Systems Quality Assessment revealed the following statement: "Purpose: To monitor, assess, and when indicated, correct problems identified in the preanalytic, analytic and post-analytic systems." 2. Review of the laboratory Mohs procedure manual revealed the following: Surgical case number: "The next available case number in the logbook is assigned to that patient. Numbers are assigned as such "JC" followed by the 2-digit year, followed by the serially numbered accession number for that patient. Numbers re-set each calendar year at 0001." The accession number is noted on chuck pad, on Tefla pad, on each frozen section slide, each patient photo and in the Mohs case log book. "Correct identification of test specimens throughout the entire Mohs surgical procedure is of utmost importance and must be the primary focus of the Mohs histotechnologist." Slide labeling: Line 1-surgery accession/case# and lesion designation number Line 2-patient last name, first name (first slide of each patient) then initials on each slide thereafter Lower right corner-stage #/tissue piece # 3. Review of random patient cases revealed that the labeling system was not followed for four of four patients: JC22-001 (1st patient performed 10/10/22)-1st slide did not include first name. The Mohs accessioning log did include complete labeling to include the "JC" designation or the year. JC22-100 (performed 12/12/22)-1st slide did not include first name. The Mohs accessioning log did include complete labeling to include the "JC" designation or the year. JC23-032 (performed 01/19/23)-1st slide did not include first name. The Mohs accessioning log did include complete labeling to include the "JC" designation or the year. JC23-074 (performed 02/09/23)-1 slide did not include first name. The Mohs accessioning log did include complete labeling to include the "JC" designation or the year. Further review of the accessioning log revealed the laboratory's procedure for accessioning had not been followed since the first patient case performed on 10/10/22 until the date of the survey on 02/13/23. 4. Request on 02/13/23 at 11:00 am for quality assessment documentation and corrective actions for errors in patient accessioning revealed no documentation of quality assessment reviews since patient testing began on 10/10/2022. 5. Interview with the lab director on 02/13/23 at 12:15 pm confirmed the laboratory had not performed any quality assessment reviews to include detection and correction of preanalytic system activities from the time patient testing began on 10/10/22 until the date of the survey on 02/13/23.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of patient data logs and final patient test reports, the laboratory quality assessment plan, lack of records and interview with the laboratory director, the laboratory failed to follow the quality assessment plan for post-analytic systems in 2022 and 2023. The findings include: 1. Review of patient data logs and final patient test reports for scabies and fungal elements revealed a discrepancy between the recorded results and the final patient result for one of three selected patients as follows: Patient 99712293--result log recorded as negative, result recorded in patient

	record as 'KOH equivocal." 2. Review of the laboratory quality assessment plan revealed the laboratory would "monitor, assess, and when indicated, correct problems identified in the preanalytic, analytic and post-analytic systems." 3. Request for quality assessment reviews on 02/13/23 at 10:15 am revealed no documents were available. 4. Interview with the laboratory director on 02/13/23 at 12:15 pm confirmed there was no documentation of quality assessment reviews. The patient data log revealed patient testing beginning 08/25/22 with seven patients recorded on the test log.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), review of provider microscopy verification of accuracy documentation, and review of personnel records, the lab director failed to delegate to testing personnel performance of provider microscopy and failed to delegate verification of accuracy procedures to a person not listed on the Form CMS-209 in 2022. The findings include: 1. The Form CMS-209 listed two testing personnel who perform provider microscopy for fungal elements and scabies. 2. Review of the verification of accuracy documents for fungal elements and scabies performed in 2022 were signed by a person not listed on the Form CMS-209. 4. There were no job descriptions/delegations for the two testing personnel performing the microscopy procedures or for the person assessing accuracy of provider microscopy procedures.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209) , testing personnel records, patient test

	logs and interview with the lab director, the lab director failed to ensure two of two testing personnel had documentation of training and demonstration of accuracy for performing provider microscopy procedures prior to patient testing in 2022. The findings include: 1. Review of the Form CMS-209 revealed two testing persons who perform provider microscopy for fungal elements and scabies. 2. Review of personnel records revealed no documentation of training and initial evaluation of accuracy for performing the provider microscopy for either testing person. 3. Review of patient test logs revealed performance of microscopy procedures for fungal elements and scabies by both testing personnel in 2022 and 2023. 4. Interview with the lab director on 02/13 /23 at 12:15 pm confirmed that neither of the two mid-level practitioners had documentation of training and initial demonstration of accurate test performance for performing provider microscopy for detection of fungal elements and scabies prior to patient testing in 2022.