Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1102639	01/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Ascension Seton Health Center	5235 Overpass Road, Suite 200, Buda, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the competency evaluations, pre-survey paperwork, and interview, the laboratory failed to assess competency for the position of Technical Supervisor for one of two Technical Supervisors. Findings follow. A. Review of competency evaluations showed none for the position of Technical Supervisor. B. Review of the Laboratory Personnel form showed the Laboratory Director acted in the role of Technical Supervisor #1, and Technical Supervisor #2 had been employed since 2013. C. Interview with the histotechnician on January 12, 2023, at 1220 hours in the Mohs lab confirmed there was no competency evaluation for the position of Technical Supervisor.
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 policies and procedures, accuracy assessments, patient logs, and interview, the laboratory failed to verify the accuracy of dermatopathology interpretations (diagnosis) of its frozen section biopsies at least twice annually for two of two years reviewed in 2021 and 2022. Findings follow. A. Review of the laboratory's policy and procedure titled Quality Assurance/Quality Management Program Mohs Surgery did not include accuracy assessments for frozen section biopsies. B. Review of accuracy assessments for dermatopathology interpretations of frozen section biopsies showed one performed in 2021, and one performed in 2022. C. Review of an email from the histotechnologist on January 25, 2023, at 3:31pm reported the annual test volume for frozen section biopsies at 16 cases. D. Interview with the histotechnologist on January 12, 2023, at 1000 hours in the laboratory confirmed Mohs checked for clear margins, and with a frozen section biopsy, a diagnosis was made. Further interview with the histotechnologist on January 12, 2023, at 1020 hours in the laboratory they only had one accuracy assessment for frozen section biopsies performed in 2021 and 2022 because the quizzes were intended to be used as competency evaluations for the Technical Supervisor, other than the Laboratory Director.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, slides, and interview, the laboratory failed to correctly label a slide used in Mohs for one of 10 cases reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Mohs Frozen Sectioning Procedure, revised 3/02/22, starting under Quality Control stated, "1. Chuck should have the patient's last name, or initials, and the assigned site number. 2. Correlate patient name and site number on chuck and slide before placing tissue section on slide. 3. Keep the cutting area clean. 4. Run a control slide prior to staining routine slides. 5. All competed slides will have the patient's last name, first initial, date of procedure, site number, and the sequential tumor number. Procedure: I. Mohs Frozen Sections: 1. Once tissue is oriented and frozen, place the chuck on the cutting arm in the cryostat. 2. Face the tissue by advancing until the tissue face starts to show. 3. Once the tissue becomes visible, begin sectioning the tissue adjusting the microns to desired thickness. 4. Place the first section on the slide closest to the labeled end. 5. Continue to section, placing several sections on the slide, until ALL epidermis is visualized. Routinely 3-4 sections may be cut, however due [to] the size of the tissue there may only be room for 1 section per slide. In this case 4 separate slides may be used. 6. After the first slide is cut, check under the microscope to make sure all epidermis is visible. If not, adjust the angle of the chuck and cut another section. Continue checking after each cut until full epidermis is visible. A third slide may be necessary, labeled 1.3 or 2.3, 3.3, etc. respectively. 7. Place the slide in a Coplin jar containing 95% alcohol to fix the tissue. 8. Place slide on the ski stainer. 9. Once completely stained, coverslip the slide and place on a slide tray with the site numbers in order, and the corresponding Mohs map, to be read by the dermatologist.

	10. Be sure to maintain chuck orientation should the dermatologist need additional sections later. 11. At the end of Mohs surgery for the day, remove all frozen tissue and allow Neg 50 (OCT) to melt. Take the melted tissue and discard in a biohazard wash receptacle. 12. Perform daily cryostat disinfection. 13. Label slides with the respective tumor numbers, with reference to the Mohs case log." B. Review of the slides for one of 10 cases showed one case had one of three slides mislabeled. Case #BT22-691 had one slide with the name from case #BT22-686. Looking at the succession of specimen on the slides, the slide labeled #BT22-691 1:3 belonged to case #BT22-686 1:3. C. Interview with the histotechnician on January 12, 2023, at 1155 hours in the Mohs lab confirmed the findings.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of competency evaluations, pre-survey paperwork, and interview, the technical supervisor failed to ensure competency evaluations for dermatopathology interpretations for frozen section biopsies and Mohs were performed that covered the six elements for two of two years reviewed for one of two testing personnel. Findings follow. A. Review of competency evaluations showed none available for review. Competency evaluations were requested on January 12, 2023, at 1000 hours but not provided. A competency quiz for the accuracy of dermatopathology interpretations was provided. The competency quiz was one component to the competency evaluation for dermatopathology interpretations for frozen section biopsies. The procedures for evaluation of the competency of the staff must include, but are not limited to- 1. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; 2. Monitoring the recording and reporting of test results; 3. Review of intermediate test results or worksheets, quality control records, proficiency testing records, and preventive maintenance records; 4. Direct observation of performance of instrument maintenance and function checks; 5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and 6. Assessment of problem-solving skills. B. Review of the CMS Form 209 showed testing personnel #1 also served as Laboratory Director. Review of the Laboratory Personnel form showed testing personnel #2 was hired in 2013. C. Interview with the histotechnician on January 12, 2023, at 1000 confirmed the findings.