Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0527073	(X3) Date Survey Completed 11/16/2023
Name of Provider or Supplier Arizona Center For Hematology And Oncology	**Street Address, City, State** 9250 N 3rd St Ste 3017, Phoenix, AZ	
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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of Mohs slides and interview with the facility personnel, the laboratory failed to ensure positive identification of one out of three patient specimens from the time of collection through completion of testing and reporting of test results. Findings include: 1. The laboratory performs Mohs testing under the subspecialty of Histopathology, with an annual test volume of 1,500. It is the practice of the laboratory to assign a unique accession number to each Mohs case which is manually recorded by laboratory personnel on the Mohs log, patient's Mohs Map, patient's slides and the final test report maintained in the patient's Electronic Medical Record (EMR). 2. The laboratory failed to ensure positive identification of a patient's specimen throughout the entire test process for one out of three Mohs cases reviewed during the survey, MS23-587 performed on 5/19/2023. The case number manually scribed on the patient's slides was illegible. 3. The facility personnel interviewed on 11/16/2023 at 10:10 AM acknowledged that the laboratory failed to ensure positive identification of the patient's specimens from the time of collection through completion of testing and reporting of results, as evidenced by the illegible case number manually scribed on the slides indicated above.
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 lack of humidity records for review from 2021, 2022 and 2023, review of the manufacturer's specifications for the cryostat, and interview with the facility personnel, the laboratory failed to monitor and document the humidity of the area where the cryostat is utilized. Findings include: 1. The laboratory uses the Leica CM1850 Cryostat to process patient samples for Mohs testing. The laboratory's reported annual test volume in the subspecialty of Histopathology is 1,500. 2. The manufacturer's specifications for the Leica CM1850 Cryostat reviewed during the survey listed an operating relative humidity range not to exceed 80%. 3. No documentation was provided for review during the survey to indicate the laboratory monitored and documented the humidity of the room where the cryostat is utilized for each day of patient testing during 2021, 2022 and 2023, through the date of the survey. 4. The facility personnel interviewed on 11/16/2023 at 10:20 AM confirmed the laboratory failed to monitor and document the humidity of the room where the cryostat is operated.
D5607	HISTOPATHOLOGY CFR(s): 493.1273(d)(f) (d) Tissue pathology reports must be signed by an individual qualified as specified in paragraph (b) or, as appropriate, paragraph (c) of this section. If a computer report is generated with an electronic signature, it must be authorized by the individual who performed the examination and made the diagnosis. (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 tissue pathology reports and interview with the facility personnel, the qualified individual who performed the examination and made the diagnosis failed to sign the Mohs Map for one out of three patient test reports reviewed during the survey. Findings include: 1. The laboratory performs patient testing in the subspecialty of Histopathology, with an approximate annual test volume of 1,500. 2. One out of three Mohs maps (MS21-1273) reviewed in the Electronic Health Record (EHR) failed to include the signature of the individual who performed the examination and made the diagnosis. 3. The facility personnel interviewed on 11/16 /2023 at 09:30 AM confirmed the Mohs Map indicated above was not signed by the individual who performed the examination and made the diagnosis.