Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0527073	10/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Arizona Center For Hematology And Oncology	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
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 lack of competency policies and procedures for review and interview with the facility personnel, the laboratory failed to establish policies and procedures to assess employee competency. Findings include: 1. The laboratory performs the grossing procedure on patient specimens under the sub-specialty of Histopathology, with an approximate annual test volume of 6,500. 2. No documentation was presented for review to indicate the laboratory established policies and procedures to assess the competency of individuals who perform the gross evaluation on histopathology specimens. 3. The facility personnel confirmed that the laboratory did not have a policy established to assess the competency of testing personnel who perform the gross evaluation on histopathology specimens.
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 lack of accuracy verification documentation and interview with the facility personnel, the laboratory failed to verify the accuracy of dermatopathology testing at least twice annually during 2016 and 2017. Findings include: 1. The laboratory

	performs Mohs testing and biopsy interpretations under the sub-specialty of Histopathology, with an approximate annual test volume of 6,500. 2. It is the practice of the laboratory to perform accuracy verification every six months, by sending a minimum of 3 Mohs cases and 2 Biopsy cases to an outside facility for accuracy assessment. 3. On the date of the survey, October 30, 2018, the laboratory failed to present documentation of accuracy verification for Mohs cases and biopsy readings and interpretations that were performed by the laboratory in 2016 and 2017. The facility personnel stated that the laboratory performed the accuracy verification procedures during each respective year, however the original documenation was destroyed. 4. The facility personnel confirmed that the laboratory failed to produce evidence of accuracy verification for testing performed by the laboratory, as indicated above.
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 patients' electronic test reports and interview with the facility personnel, the laboratory failed to have one out of one pathology reports signed by the individual who performed the examination and made the diagnosis. Findings include: 1. The laboratory performs patient testing under the sub-specialty of Histopathology, with an approximate annual test volume of 6,500. The laboratory performs biopsy interpretations on patient specimens. It is the practice of the laboratory to record pathology reports in the Electronic Medical Record (EMR). 2. No documentation of a signed pathology report was presented for review in the EMR or elsewhere in the laboratory for a biopsy performed on patient M.W. on 04/02/2018. 3. The facility personnel confirmed that the laboratory failed to maintain a signed pathology report in the EMR for the biopsy case indicated above.
D6128	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 annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on lack of testing personnel competency evaluation documentation and interview with the facility personnel, it was determined that the technical supervisor failed to evaluate and document the performance of one testing personnel at least annually. Findings include: 1. The laboratory performs testing under the sub-specialty of Histopathology, with an approximate annual test volume of 6,500. 2. No documentation of annual competency assessment for 2016 and 2017 was presented for

	review for one out of one testing personnel who performs the gross description on patient specimens. 3. The facility personnel confirmed that no annual competency evaluation was performed for the testing personnel indicated above during 2016 and 2017.