Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D1084762	03/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Arizona Center For Cancer Care	18699 N 67th Ave Ste 230, Glendale, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on lack of manufacturer's package inserts presented for review for the UroVysion FISH (Fluorescence In Situ Hybridization) test and FISH probe kit and interview with the facility personnel, the laboratory failed to retain the manufacturer's package insert for at least 2 years for each lot of test kits and probe kits used by the laboratory. Findings include: 1. The laboratory performs the UroVysion FISH test under the sub-specialty of General Immunology, with an approximate annual test volume of 630. 2. During the survey conducted on March 9, 2021, no evidence was presented for review to indicate the laboratory retained the manufacturer's package inserts for at least 2 years for each lot of UroVysion FISH test kit and FISH probe kits that were used for testing by the laboratory. The manufacturer's package insert contains information specific to the lot number and expiration date of each test kit and each probe kit. 3. Each patient test report for the UroVysion FISH test (AC21-00251, AC20-01457 and AC21-00203) reviewed during the survey contained an enumeration report form which was completed by the testing personnel. Each enumeration report form listed the specific UroVysion Probe Lot number, but failed to include the corresponding expiration date. 4. The facility personnel confirmed that the laboratory failed to retain the manufacturer's package insert for at least 2 years for each lot of the UroVysion FISH test and FISH probe kit used for patient testing.
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 established policies for the UroVysion FISH (Fluorescence In Situ Hybridization) test and interview with the facility personnel, the laboratory failed to follow policies and procedures to assess employee competency. Findings include: 1. The laboratory performs FISH testing under the sub-specialty of General Immunology, with an approximate annual test volume of 630. 2. The laboratory policy reviewed during the survey titled, "UroVysion FISH Testing" states, "Competency assessments will be performed twice annually on all personnel performing this test." 3. No evidence was presented for review to indicate the laboratory performed a competency assessment twice annually for one testing personnel who began FISH testing on patient specimens in February 2020. 4. The facility personnel confirmed that the laboratory failed to perform a competency assessment twice annually for the testing personnel indicated above.
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 for review and interview with the facility personnel, the laboratory failed to verify the accuracy of FISH (Fluorescence In Situ Hybridization) testing at least twice annually during 2019 and 2020. Findings include: 1. The laboratory performs FISH testing under the sub-specialty of General Immunology, with an approximate annual test volume of 630. 2. No documentation was presented for review during the survey conducted on March 9, 2021 to indicate the laboratory verified the accuracy of FISH testing at least twice annually during 2019 and 2020. 3. The laboratory's policy titled, "Section 12 UroVysion FISH" states, "Twice a year a blind study is conducted on the enumeration of cells for UroVysion. One tech manually scores the case and records their datasets. The second tech then scores the same case and records their datasets. The results are then compared for accuracy". 4. The facility personnel confirmed that the laboratory failed to verify the accuracy of the FISH test during 2019 and 2020.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on lack of Quality Assessment (QA) documentation, lack of accuracy verification records for testing performed by the laboratory, lack of employee

	competency records and interview with the facility personnel, the laboratory failed to follow established policies and procedures for an ongoing mechanism to monitor, assess, and when indicated correct problems identified in the general laboratory systems. Findings include: 1. No QA documentation was presented for review during the survey conducted on March 9, 2021 to indicate the laboratory performed and documented QA activities in order to identify and correct errors associated with a lack of accuracy verification for FISH testing. See D5217 for findings. 2. No QA documentation was presented for review during the survey conducted on March 9, 2021 to indicate the laboratory performed and documented QA activities in order to identify and correct errors associated with a lack of personnel competency performance. See D5209 for findings. 3. The facility personnel confirmed that the laboratory's QA processes at the time of the survey conducted on 3/09/2021 were not effective at monitoring, identifying and correcting problems associated with the general laboratory systems.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the number and severity of deficiencies cited for quality control practices identified during the survey conducted on March 9, 2021, it was determined that the laboratory failed to monitor the overall quality of the analytic systems and correct problems as specified in 493.1289 for patient testing performed by the laboratory in the sub- specialty of General Immunology. See D5445 and D5791 for findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of Quality Control (QC) documentation for UroVysion FISH testing and interview with the facility personnel, the laboratory failed to perform and document control procedures as required for UroVysion FISH testing, using the number and frequency specified by the manufacturer. Findings include: 1. The laboratory performs FISH testing under the sub-specialty of General Immunology, with an approximate annual test volume of 630. 2. No evidence was presented for

	review during the survey conducted on March 9, 2021 to indicate the laboratory performed and documented QC for UroVysion FISH testing performed from January 2019 through the date of the survey conducted on March 9, 2021. 3. The manufacturer's instructions for the 'UroVysion Bladder Cancer Kit' state, "Control slides must be run concurrently with patient slides to monitor assay performance and to assess the accuracy of signal viewing. One control slide (1 positive and 1 negative target per slide) must be processed for each specimen processing run, and with each new kit lot. Control slides must be hybridized with the UroVysion probe mixture along with study specimen slides". 4. The laboratory's established policy titled, "UroVysion FISH Testing", reviewed during the survey states, "A control slide containing known normal and abnormal cells, will be processed concurrently with each batch of patient slides. A minimum of 25 normal and 25 abnormal cells must be observed with a minimum hybridization efficiency rating of 3, "moderate" for control slide to be considered "passing"." 5. The facility personnel confirmed that the laboratory failed to perform QC on the UroVysion FISH test as indicated above.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of Quality Assessment (QA) policies, lack of Quality Control (QC) records, and interview with the facility personnel, the laboratory failed to identify problems associated with a lack of Quality Control performance for the UroVysion FISH test. Findings include: 1. The laboratory's policy reviewed during the survey titled, "Section 17 Quality Control Programs" states, "FISH assay images and slides with IHC assays are closely assessed by the pathologist. Positive and negative controls are checked." 2. No QA documentation was presented for review during the survey to indicate the laboratory identified issues found with the lack of QC performance from January 2019 through the date of the survey conducted on March 9, 2021 for the UroVysion FISH assay. See D5445 for findings. 3. The facility personnel acknowledged that the laboratory's QA process at the time of the survey failed to identify whether or not QC was performed and acceptable each day of patient testing.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: The Condition of Laboratory Director is not met as evidenced by: D6093 - failure to ensure that the laboratory maintains quality control programs to assure quality results; D6094 - failure to ensure that the laboratory maintains a quality assessment program to identify and correct errors as they occur and, D6102 - failure to ensure that all testing personnel have the appropriate education and experience, receive the

	appropriate training and demonstrate that they can perform all testing operations reliably and accurately prior to testing patients' specimens.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on lack of quality control records and review of control procedures, the laboratory director failed to ensure that quality control programs are maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5445 and D5791 for findings.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on lack of quality assessment (QA) documentation for review, the laboratory director failed to ensure that a QA program is established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5291 and D5791 for findings.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 (A) lack of education documentation for one individual listed on the CMS-209, Laboratory Personnel form and (B) lack of training documentation for one testing personnel who performs testing in the sub-specialties of Histopathology and General Immunology and interview with the facility personnel, the laboratory director failed to ensure that all testing personnel have the appropriate education and experience, receive the appropriate training and demonstrate that they can perform all testing operations reliably and accurately prior to testing patients' specimens. Findings include: A1. The CMS-209, Laboratory Personnel Form submitted for review during the survey conducted on March 9, 2021 listed one testing personnel hired in October 2020 to perform grossing on patient specimens in the sub-specialty of Histopathology. A2. No documentation of appropriate education credentials was presented for review

	during the survey to indicate the laboratory personnel indicated above was qualified to perform high complexity testing under the sub-specialty of Histopathology. A3. The facility personnel confirmed that the individual referenced above lacked the appropriate education for high complexity testing performed by the laboratory. B1. No initial training documentation was presented for review for one testing personnel hired in February 2020, who performs grossing on patient specimens in the sub-specialty of Histopathology. B2. No initial training documentation, including evidence of a visual color test, was presented for review for one out of one testing personnel who performs the count (signal enumeration) for FISH testing on patient specimens in the sub-specialty of General Immunology. The testing personnel was hired in Februaury 2020. B3. The manufacturer's instructions for the UroVysion FISH assay state, "Technologists performing the FISH signal enumeration must be capable of visually distinguishing between the red, green, aqua and orange signals". B4. The facility personnel confirmed that the laboratory failed to have documentation of initial training for the testing personnel indicated above.
D6127	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on lack of documentation of a semi-annual competency evaluation for one testing personnel and interview with the facility personnel, the technical supervisor failed to evaluate and document the performance of individuals responsible for high complexity testing at least semiannually during the first year the individuals tested patient specimens. Findings include: 1. No semi-annual competency evaluation documentation was presented for review for one testing personnel who began FISH testing on patient specimens in February 2020. 2. No semi-annual competency evaluation documentation was presented for review for one testing personnel who began grossing patient specimens in February 2020. 3. The facility personnel confirmed that the laboratory failed to have documentation of a semi-annual competency evaluation for the testing personnel indicated above.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or

medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on lack of education documentation presented for review during the survey for one testing personnel, the laboratory failed to ensure that testing personnel have the required education qualifications prior to testing patients' specimens. Findings include: 1. The laboratory performs grossing on approximately 835 specimens annually, under the sub-specialty of Histopathology. 2. The CMS-209, Laboratory Personnel form submitted for review during the survey conducted on March 9, 2021 indicated one testing personnel who began grossing patient specimens in October 2020. 3. No documentation was presented for review during the survey to indicate the testing personnel referenced above met the required qualifications under 493.1489 in the CLIA regulations for Testing Personnel who perform high complexity testing. 4. The facility personnel confirmed that the testing personnel stated above lacked the appropriate education documentation for the complexity of testing performed by the

	laboratory.