

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D1084762	(X3) Date Survey Completed 10/24/2018
Name of Provider or Supplier Arizona Center For Cancer Care	Street Address, City, State 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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's UroVysion FISH test procedure manual and interview with the facility personnel, the laboratory failed to have the current laboratory director approve and sign test procedures before use. Findings include: 1. The laboratory began the UroVysion FISH test in April 2018. 2. The UroVysion FISH procedure manual presented for review during the survey conducted on October 24, 2018 was not approved, signed and dated by the current laboratory director. 3. The facility personnel confirmed that the procedure manual indicated above was not approved, signed and dated by the current laboratory director before use.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on lack of maintenance policies for review and interview with the facility</p>

personnel, the laboratory (A) failed to establish a microscope maintenance policy that indicates specific routine maintenance procedures as well as scheduled preventative maintenance procedures and (B) failed to establish a policy and procedure for performing function checks on the centrifuge. Findings include: A1. The policy and procedure manual presented for review during the survey conducted on October 24, 2018 did not contain any policies with regards to microscope maintenance. A2. The facility personnel acknowledged that there was no microscope maintenance policy contained in the manual. A3. The laboratory has an Acuscope Fluorescence microscope used to perform the count for the UroVysion FISH test. B1. The policy and procedure manual presented for review during the survey conducted on October 24, 2018 did not contain any policies and procedures for performing function checks on the centrifuge. B2. The facility personnel confirmed that the laboratory did not have an established policy and procedure for performing function checks on the centrifuge. B3. The centrifuge is used for processing urine specimens for the UroVysion FISH test.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of patient test reports generated from the Laboratory Information System (LIS) and interview with the facility personnel, the laboratory failed to indicate the correct name and address on the test reports for testing that was performed at the facility. Findings include: 1. The laboratory listed under CLIA# 03D1084762, located at 18699 N 67th Ave Ste 230, Glendale, AZ 85308, performs patient testing under the specialty of Pathology, with an approximate annual test volume of 12,000. The laboratory performs the technical component or gross description on histology and cytology specimens, as well as process the specimens for interpretation. 2. During the survey conducted on October 24, 2018, one out of one patient test report reviewed (AS18-00010) indicated "Technical Component Performed at: Arizona Center for Cancer Care, 5750 W Thunderbird Rd. Ste 230, Glendale, AZ 85306". 3. The facility personnel confirmed that the laboratory name and address listed on the test report indicated above was incorrect.