Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D2126395	12/06/2022
Name of Provider or Supplier	**Street Address, City, State**	
Optumcare Cancer Care-Ft Apache Rd	6190 S Fort Apache Rd, Las Vegas, NV	

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	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on December 6, 2022. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of the College of American Pathologist (CAP) proficiency test results for Hematology for testing years 2021 and 2022, and an interview with the laboratory manager, the laboratory failed to identify and document corrective action for unacceptable proficiency test results. Findings include: 1. The laboratory documented the review of the CAP second event FH2-B 2022 Hematology proficiency test results that were received, but failed to identify and document an assessment of the unacceptable White Blood Cell (WBC) count for specimen FH2-10. 2. The laboratory result for the WBC count for specimen FH2-10 was 5.0 when the acceptable range for the WBC was 3.2 to 4.5. 3. The director approved policy and procedure manual that relates to Proficiency Testing states in section 32.1 that "A survey evaluation with a flagged result, or result with an asterisk, indicates an

	unacceptable result". In section 32.2, the policy states that, "Clinic nursing leadership and the PAD Department Project Manager will complete an assessment of the failure". 4. The laboratory manager confirmed this at approximately 10:00 am on December 6, 2022. The laboratory performs approximately 5,000 Hematology tests annually.
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 a review of the director approved policy and procedure manual, and an interview with the laboratory manager, the laboratory failed to have an established procedure to perform, document and evaluate an alternative assessment of laboratory proficiency testing when a proficiency testing organization's testing event is not available. Findings include: 1. The laboratory failed to perform an alternative testing assessment when the second event AQI-B 2022 CAP proficiency testing specimens were received twice by the laboratory in an unsatisfactory manner. 2. The laboratory contacted CAP to inform the proficiency testing agency that the specimens were twice received warm and that the results of the testing would be unreliable. The CAP agency informed the laboratory that there were no additional specimens that could be sent for the second event AQI-B 2022. 3. The laboratory entered the exception code "33" for the event due to the unacceptable specimens that were received. The CAP instructions for code "33" stated, "Document that the laboratory has contacted the CAP and no replacement specimens were available. Perform and document alternative assessment (ie, split samples) for the period that commercial PT was not tested to the same level and extent that would have been tested". This was not performed or documented by the laboratory. 4. There was no director approved policy and procedure available at the time of inspection to perform, document or evaluate alternative proficiency testing assessment. This was confirmed by the laboratory manager on December 6, 2022 at approximately 10:30 am. The laboratory performs approximately 500 Chemistry tests annually.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on a review of the CAP proficiency testing results for testing years 2021 and 2022 for Hematology and Chemistry, and an interview with the laboratory manager, the laboratory director failed to ensure a corrective action plan is established and

	followed when proficiency testing results are found to be unsatisfactory or unacceptable. Findings include: 1. The laboratory director failed to have an established policy and procedure to document and provide an evaluation for an alternative proficiency testing assessment when a proficiency testing agency is not able to provide specimens for a testing event. 2. The laboratory director failed to ensure that unacceptable proficiency test results for any analyte, are assessed to determine the cause for the unacceptable result with documentation of the assessment. This was confirmed by the laboratory manager on December 6, 2022 at approximately 11:00 am. The laboratory perform approximately 500 Chemistry tests and 5,000 Hematology tests annually.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of director approved policy and procedure manual, and an interview with the laboratory manager, the laboratory director failed to have an established policy and procedure for the quality assessment of the laboratory services. Findings include: 1. The laboratory director failed to have a quality assessment policy and procedure established to evaluate the pre-analytic, analytic and post-analytic phases of laboratory testing which would include elements for the evaluation and areas of corrective action as needed. 2. The laboratory initially began performing monthly laboratory assessments, but later changed to performing assessments quarterly with no indication that this was an acceptable practice that was approved by the laboratory director. 3. The quarterly quality assessment that was being performed, indicated a review of proficiency testing in which the element that was reviewed stated, "Proficiency Testing Results are 100 % acceptable". The quarterly documented review failed to capture the WBC specimen from the second event FH2-B Hematology proficiency testing that had an unacceptable result for FH2-10 and the unacceptable specimens for the second event AQI-B 2022 where there was no alternative testing assessment performed. This was confirmed by the laboratory manager on December 6, 2022 at approximately 11:00 am. The laboratory perform approximately 500 Chemistry tests and 5,000 Hematology tests annually.