Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D2137199	01/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Optumcare Cancer Care-Seven Hills	3175 St Rose Pkwy Ste 200, Henderson, 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 January 25, 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.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of the 2019, 2020, and 2021 College of American Pathologists (CAP) proficiency testing (PT) records, and an interview with the laboratory Project Manager and Practice Manager, the laboratory failed to ensure that the attestation statements provided by the proficiency testing (PT) program documenting that the PT samples were tested in the same manner as patient samples were signed by the laboratory director, and by the testing personnel. Findings include: 1. A review of the College of American Pathologists (CAP) proficiency testing (PT) records revealed that the laboratory director failed to sign the attestation stating that the PT specimens

	were tested in the same manner as patient samples for the 2020 and 2021 Critical Care Blood Gas with Chemistry I-Stat (AQI) tests events A, B, and C; and for the 2020 and 2021 Hematology Automated Differential Series (FH-2) test events A, B, and C. 2. A review of the College of American Pathologists (CAP) proficiency testing (PT) records revealed that one of one testing personnel failed to sign the attestation stating that the PT specimens were tested in the same manner as patient samples for the 2019 Critical Care Blood Gas with Chemistry I-Stat (AQI) test event B; two of two testing personnel failed to sign the attestation stating that the PT specimens were tested in the same manner as patient samples for the 2019 Critical Care Blood Gas with Chemistry I-Stat (AQI) test event C; and one of one testing personnel failed to sign the attestation stating that the PT specimens were tested in the same manner as patient specimens for the 2019 Hematology Automated Differential Series (FH-2) test event C. 3. The laboratory project manager and the laboratory practice manager confirmed the findings during an interview conducted on January 25, 2022 at approximately 10: 00 AM. The laboratory performs approximately 300 chemistry tests and 7000 hematology tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the operator's manual for the Abbott i-STAT manual, the lack of laboratory documentation of the i-STAT thermal probe checks for 2019, 2020, and 2021, and an interview with the laboratory project manager and laboratory practice manager, the laboratory failed to document the i-STAT thermal probe check twice per year. Findings include: 1. There was no documentation of the performance of the i-STAT thermal probe check every six months when the External Electronic Simulator is used routinely but the results are not transmitted to a Central Data Station (CDS), or twice per year when the Internal Electronic Simulator is used routinely but the results are not transmitted to a Central Data Station (CDS). 2. The Abbott i-STAT operator's manual stated in Chapter 14, in the section entitled, "Checking the Thermal Probes in the i-STAT Analyzer," on page 14-16, "Verify the thermal probe check for the i-STAT 1 Analyzer as follows: External Electronic Simulator used routinely, results not transmitted to a Central Data Station: Use the procedure below to check the thermal probes on each analyzer every six months. Internal Electronic Simulaator used routinely: Use the procedure below to check the thermal probes on each analyzer twice per year." 3. The laboratory project manager and the laboratory practice manager stated during an interview conducted on January 25, 2022 at approximately 12:45 PM that the thermal probe checks were performed every six months at the time of software updates on the analyzer, but that the results of the thermal probe checks were not documented. The laboratory performs approximately 300 chemistry tests annually.
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 a review of the laboratory room and refrigerator temperature records, and an interview with the laboratory project manager and laboratory practice manager, the laboratory failed to ensure the temperature logs were reviewed and signed as part of the monthly laboratory quality assessment process. Findings include: 1. A review of the monthly laboratory refrigerator and room temperature logs between the dates of July, 2019 and December, 2021 revealed that there was no documentation to indicate that the temperature logs were reviewed and signed as reviewed by the practice manager in the designated area on the second page of the temperature logs. 2. The findings were confirmed during an interview with the laboratory project manager, and the laboratory practice manager during an interview conducted on January 25, 2022 at approximately 11:45 AM. The laboratory performs approximately 300 chemistry tests and 7000 hematology tests annually.