Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0861378	01/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Oncology Consultants	2130 W Holcombe Blvd 10th Floor, Houston, TX	

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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy, surveyor observation of the laboratory, a review of the laboratory's submitted CMS 116 form, and staff interview, it was revealed that the laboratory failed to document the revised expiration date on eight of eight individual Abbott i-STAT Chem 8+ cartridges found in the laboratory being stored at room temperature. Findings include: 1. A review of the laboratory's policy titled 'i-STAT Chem 8+ Operational Procedure' revealed the following: "Once opened Store cartridges at room temperature 18 to 30 degrees Celsius and calculate the expiration date by counting 14 days (including the day removed from refrigeration) and mark it on the box/cartridge in the appropriate place. NOTE: If the individual cartridge is not used on the day it is removed from the refrigerator, use a soft felt pen to mark the room temperature expiration date on the pack, taking care not to puncture the pack. Do not use cartridge if this date has passed." 2. Surveyor observation of the laboratory on 1/12/23 at 12:20 p.m. revealed 8 Abbott i-STAT Chem 8+ cartridges (lot H22307, expiration date: 5/2/23) on the counter being stored at room temperature. 3. Further review of the 8 cartridges revealed no open date or revised expiration date were documented on the pack. 4. A review of the laboratory's submitted CMS 116

	application revealed the laboratory indicated the estimated annual test volume for i-STAT Chem 8+ testing at 4000. 5. An interview with the laboratory manager on 1/12 /23 at 12:40 p.m. in the laboratory, after review of the records, confirmed the above findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory's quality control records for the Abbott i-STAT analyzer from September 2022 to January 2023 and staff interview, it was revealed that the laboratory failed to have a method in place to monitor quality control values over time to detect shifts and trends for eight of eight analytes tested on the Abbott i-STAT analyzer. Findings include: 1. A review of the laboratory's quality control records for the Abbott i-STAT analyzer (serial number: 328049) from September 2022 to January 2023 revealed the laboratory ran the Abbott Tricontrols, levels 1 and 3, with every new lot/shipment of cartridges or control material or every 30 days. 2. Further review of the quality control records revealed the laboratory ran the following lot numbers of Tricontrol quality control material (levels 1 and 3) on the following days: - Date: 9/1/22 Level 1 lot number: 301151 Level 3 lot number: 321151 - Date: 10/3/22 Level 1 lot number: 301151 Level 3 lot number: 321146 - Date: 10/20/22 Level 1 lot number: 301151 Level 3 lot number: 321146 - Date: 11/1/22 Level 1 lot number: 301151 Level 3 lot number: 321146 - Date: 12/1/22 Level 1 lot number: 301151 Level 3 lot number: 321146 - Date 12/8/22 Level 1 lot number: 301145 Level 3 lot number: 321146 - Date: 1/3/23 Level 1 lot number: 301145 Level 3 lot number: 321146 3. Further review of the quality control records revealed the laboratory failed to have a method in place for monitoring and evaluating quality control results over time for the following 8 analytes tested on the Abbott i-STAT analyzer: Sodium Potassium Chloride Ionized Calcium Total Carbon Dioxide Glucose Blood Urea Nitrogen Creatinine 4. An interview with the laboratory manager on 1/12/23 at 11:30 a.m. in the conference room revealed the laboratory only assessed quality control values on the day they are run and did not monitor or evaluate values over time for shifts or trends. This confirmed the above findings.