Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1049999	08/02/2019
Name of Provider or Supplier	**Street Address, City, State**	
Oncology Consultants, Pa	7789 Southwest Freeway Suite 460, 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 representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory verification studies, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions for performing the method comparison on the Sysmex XN-450 hematology analyzer. Findings were: 1. Review of the manufacturer's instructions XN-series XN-L Method Verification Manual (1251-LSS, Rev 2, Dec 2016) revealed "complete blood counts samples should be analyzed within 4 hours of collection and on both analyzers within 2 hours of each other." 2. Random review of the method comparison studies of the Sysmex XN-450 hematology analyzers revealed no documentation of the collection date and time. 3. Random review of the method comparison studies of the Sysmex XN-450 hematology analyzers revealed documentation that sample analysis was not within 2 hours of each analyzer for 9 of 10 samples reviewed. Patient ID 259304 sample analyzed 7/8/19 @ 10:19 hours (Sysmex XN-450) and 16:53 hours (2nd analyzer); elapsed time 6:34 Patient ID 261009 sample analyzed 7/8/19 @ 11:05 hours (Sysmex XN-450) and 16:54 hours

	(2nd analyzer); elapsed time 5:49 Patient ID 260727 sample analyzed 7/8/19 @ 12:07 hours (Sysmex XN-450) and 16:59 hours (2nd analyzer); elapsed time 4:52 Patient ID 49804 sample analyzed 7/8/19 @ 12:09 hours (Sysmex XN-450) and 17:09 hours (2nd analyzer); elapsed time 5:00 Patient ID 79373 sample analyzed 7/8/19 @ 11:02 hours (Sysmex XN-450) and 17:21 hours (2nd analyzer); elapsed time 6:19 Patient ID 249347 sample analyzed 7/8/19 @ 14:48 hours (Sysmex XN-450) and 17:24 hours (2nd analyzer); elapsed time 2:36 Patient ID 80767 sample analyzed 7/8/19 @ 11:24 hours (Sysmex XN-450) and 17:29 hours (2nd analyzer); elapsed time 6:05 Patient ID 68830 sample analyzed 7/9/19 @ 08:17 hours (Sysmex XN-450) and 11:49 hours (2nd analyzer); elapsed time 3:32 Patient ID 261187 sample analyzed 7/9/19 @ 09:48 hours (Sysmex XN-450) and 11:52 hours (2nd analyzer); elapsed time 2:04 4. An interview with the lab manager on 8/2/19 at 1315 hours in the laboratory confirmed the above findings. She was unaware of the time limits for the method comparison study.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on a review of laboratory policy, environmental charts, patient records, and confirmed in interview, the laboratory failed to document all corrective actions when temperatures were outside of the established acceptable range. Findings were: 1. Review of the laboratory policy Equipment Maintenance revealed the room temperature acceptable range as 15-25 C. 2. Random review of the laboratory environmental records from July 2018 - July 2019 revealed 9 days when temperature was outside of the acceptable range of 15-25 C per the laboratory policy. 5/07/19 25.6 C 5/08/19 26.5 C 5/09/19 27.4 C 5/29/19 25.9 C 6/04/19 26.9 C 6/05/19 26.7 C 6/24 /19 27.4 C 6/25/19 26.1 C 6/26/19 26.1 C 3. Random review of the laboratory records revealed the laboratory performed patient testing on the above dates with no documentation of the corrective action. Date Patient ID 5/07/19 257748, 259569, 257365 5/08/19 261446, 259569, 247775 5/09/19 261446, 247164 5/29/19 254911, 262449 6/04/19 259576, 248244 6/05/19 260386, 251151 6/24/19 260799, 251941 6 /25/19 258721, 27773 6/26/19 254254, 252148 4. An interview with the laboratory manager on 8/2/19 at 1330 hours in the laboratory confirmed the above findings.
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 reports and interview, the laboratory quality assessment policies and procedures failed to identify and correct problems identified in analytical systems. Refer to D5411, D5785

D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's verification studies performed on the Sysmex XN450 hematology analyzer, review of the laboratory's personnel records, and confirmed in interview, the technical consultant failed to document competency assessments on testing personnel prior to performing patient testing. The findings were: 1. A review of the laboratory's verification studies for the Sysmex XN-450 hematology analyzer (Serial No 11996) revealed the instrument was placed into use on July 10, 2019. 2. A review of the laboratory's personnel records revealed no competency for all testing personnel (Testing person 1-4) on the Sysmex XN-450 analyzer were prior to start of patient testing on the new analyzer. 3. An interview with the lab manager on 8/2/19 at 1225 hours in the lab confirmed the above findings. She was unaware competency assessments were required prior to installing a new instrument performing the same testing already in the lab.