Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2109070	10/01/2020
Name of Provider or Supplier	**Street Address, City, State**	
Oncology Consultants Pa	1920 Country Place Parkway Ste 370, Pearland, 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 at the entrance and exit conferences. The facility representative was 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. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the

	protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory's procedure manual, review of manufacturer's instructions for the hematology analyzer, review of the quality control (QC) analysis data, and confirmed in interview with facility personnel, the laboratory failed to implement a written policy for entering QC values for new lot changes. The findings were: 1. Review of the laboratory's procedure manual, failed to include procedures for implementing QC values for new lot changes and signed and dated by the laboratory directory. 2. Review of the manufacturer's instructions for the Sysmex hematology analyzer XN-450 under "Sysmex Evidence-Based Control Limits" states " Utilizing the BeyondCare Quality Monitor (BCQM)Quality control is performed to monitor an analyzer ' s performance over time. XN-L CHECK is the material used to monitor the performance of the XN-450 analyzer. Quality control should be run in accordance with regulatory agency requirements. For the BeyondCare Quality Monitor program, a minimum of 2 levels of controls are needed to be run at least once every 24-hours. It should be noted that for troubleshooting purposes, additional control runs may be necessary. The BeyondCare Quality Monitor program that will help you determine when troubleshooting is necessary and dynamic screen prompts will guide the end user for the next action. All troubleshooting actions are logged in the Activity Log on the analyzer. Registering and modifying a QC file - lot information input a. Select [QC File] icon 2. Select a QC file that does not have a lot registered. 3. Select [Register] 4. Select [Read Assay file] 5. Select the correct QC product, lot number, and level 6. 6. Select [Ok] 7. Verify the QC lot number, level and expiration date matches the QC vials received by the lab 8. Repeat for each level of XN-L CHECK to be registered. 9. Perform parallel studies between production lot and new lot prior to production lot." 3. During an interview on 10/01/2020 at 1340 hours with the technical consultant in the laboratory confirmed they did not have a policy for implementing QC values for new lots.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, and staff interview, it was revealed the laboratory failed to document the policy manual when procedures were discontinued. The findings were: 1. A review of the laboratory's policy manual revealed, the laboratory failed to document tests or procedures with a date discontinued: a. Penta C60 7.0 Operations b. Platelet Count for Sodium Citrate tubes 7.0 A c. Westgard Evidence Based QC 3.6 d. Materials Mangement Inventory control 3.1 - marked in procedure manual discontinued with no date 2. An interview with the technical consultant on 10/1/2020 at 1410 hour confirmed the findings these procedures were not documented with no date discontinued in the policy manual.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control policy and confirmed in interview, the laboratory failed to document all post-analytical laboratory systems quality assessment activities. Findings were: 1. A review of the laboratory control policy, the laboratory failed to have a mechanism in place that would identify following manufacturer's instructions for QC files. (refer D5403) 2. An interview with the office manager on 10/01/2020 at 1345 hours in the laboratory confirmed the above findings. She was not aware the laboratory failed to utilize the manufacturer's instructions. Key: QC- Quality Control
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of laboratory records, and confirmed in interview of facility personnel revealed the laboratory director failed to authorize moderate complex testing for 7 of 8 testing personnel from 2018 to 2020. The findings were: 1. Review of laboratory records revealed the laboratory did not have a policy authorize moderate complex testing. 2. Review of personnel records revealed no authorizations were available for review for 7 of 8 testing personnel. TP #2 hired 07/09/2018 TP #3 hired 01/21/2019 TP #4 hired 10/14/2019 TP #5 hired 04/23/2020 TP #6 hired 03/02/2020 TP #7 hired 07/20/2020 TP #8 hired 08/03/2020 3. An interview with the technical consultant on 10/01/2020 in the office at 1025 hours confirmed the findings.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director

	review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory director failed to specify, in writing, the responsibilities of technical consultant. The findings were: 1. A review of the laboratory's policies revealed the laboratory did not have a documentation for initial competency for the personnel. 2. A review of the laboratory's personnel records revealed the files did not contain initial competency for 7 of 8 testing personnel. 3. The laboratory was asked to provide documentation of the laboratory director specifying the responsibilities of technical consultant to perform initial competency at the facility. 4. An interview with the technical consultant on 10/01/2020 at 1045 hours in the office revealed they had no policy performing initial competency at this facility.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing initial competency assessments on testing personnel at this facility for 2018 to 2020. The findings were: 1. A review of the laboratory's personnel records revealed 7 of 8 testing personnel at this facility did not have initial competency assessments at this facility from 2018 to 2020. 3. Seven of 8 testing personnel (as listed on CMS Form 209) competency assessments were documented as being performed by the Memorial City facility and not by the technical consultant at this facility. Testing Person hired TP #2 07/09/2018 TP #3 01/21/2019 TP #4 10/14/2019 TP #5 04/23/2020 TP #6 03/02/2020 TP #7 07/20/2020 TP #8 08/03/2020 4. An interview with technical consultant on 10/01/2020 at 1025 hours in the office revealed the initial competency assessments were performed at Memorial City office. The technical consultant stated, "She uses them for simultaneous and thought this would satisfy". This confirmed the findings.