Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0938262	10/07/2020
Name of Provider or Supplier	**Street Address, City, State**	
Oncology Consultants Pa	17520 W. Grand Parkway S. Ste 460, Sugar Land, 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. 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.
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Medical Laboratory Evaluation (MLE) proficiency testing records and staff interview, it was revealed the laboratory failed to

	participate in 1 of 3 proficiency testing events for 2019, resulting in unsatisfactory scores for all analytes in the specialty of Hematology. Findings include: 1. Review of the laboratory's Medical Laboratory Evaluation (MLE) proficiency testing records from 2019 revealed the laboratory failed to participate in the 2019 Hematology MLE - 3rd Event, resulting in an unacceptable score of 0% for the following analytes: a) White Blood Cell Count b) Red Blood Cell Count c) Hemoglobin d) Hematocrit e) Platelet Count f) White Blood Cell Differential - Neutrophils - Lymphocytes - Monocytes - Eosinophils - Basophils 2. An interview with the technical consultant (as indicated on the CMS 209 form, signed by the laboratory director on 9/29/20) on 10/7 /20 at 10:05 a.m. in the office, after review of the records, confirmed that the API was not sent in on time. This confirmed the above findings.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Medical Laboratory Evaluations (MLE) proficiency testing records from 2019 and staff interview, it was revealed the laboratory failed to retain the signed attestation statements and instrument print outs for 2 of 3 events in 2019. Findings include: 1. A review of the laboratory's Medical Laboratory Evaluations (MLE) proficiency testing records from 2019 revealed the laboratory failed to retain the signed attestation statements and instrument print outs for the following events: Hematology MLE - 2019 M1 (first event) Hematology MLE - 2019 M2 (second event) 2. The laboratory was asked to provide the missing documentation for the 2 events in 2019. No documentation was provided. 3. An interview with the technical consultant (as indicated on the CMS 209 form, signed by the laboratory director on 9/29/20) on 10/7/20 at 10:30 a.m. in the office, after review of the records, confirmed the above findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, a review of the laboratory's Refrigerator and Freezer/Room Temperature and Humidity logs for 2020, a review of patient test records, and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions when the room temperature was documented outside the laboratory's acceptable range for 5 of 5 times from January 2020 to September 2020. Findings include: 1. A review of the laboratory's policy

	titled 'Equipment Maintenance' revealed the following: "Room Temperature should range from 15 - 25 C If move out of range look for the following: - Door left open ajar - Power turned off or unplugged - Electrical power failure - Adjust thermostat - Ice buildup defrost semiannually to prevent this" 2. A review of the Refrigerator and Freezer/Room Temperature and Humidity logs for 2020 revealed the following days where the documented room temperature was outside the laboratory's acceptable range: Date Recorded Temperature 2/14/20 25.1 C 7/16/20 29.1 C 7/17/20 31.2 C 7/20 /20 26.2 C 7/21/20 25.9 C 3. The laboratory was asked to provide documentation of performing corrective actions when the room temperature was outside of the acceptable range. No documentation was provided. 4. A random review of patient records revealed the following patients were run and resulted when the laboratory's room temperature was outside of the acceptable range: Date: 2/14/20 Sample Number: 266791 Date: 2/14/20 Sample Number: 263101 Date: 2/14/20 Sample Number: 251912 Date: 2/14/20 Sample Number: 79178 Date: 2/14/20 Sample Number: 249552 Date: 7/16/20 Sample Number: 44302 Date: 7/16/20 Sample Number: 39861 Date: 7 /16/20 Sample Number: 34838 Date: 7/16/20 Sample Number: 44244 Date: 7/16/20 Sample Number: 44471 Date: 7/17/20 Sample Number: 44635 Date: 7/17/20 Sample Number: 44682 Date: 7/17/20 Sample Number: 44711 Date: 7/17/20 Sample Number: 44754 Date: 7/17/20 Sample Number: 44938 Date: 7/20/20 Sample Number: 45229 Date: 7/20/20 Sample Number: 45100 Date: 7/20/20 Sample Number: 45177 Date: 7 /20/20 Sample Number: 45052 Date: 7/20/20 Sample Number: 45118 Date: 7/21/20 Sample Number: 45818 Date: 7/21/20 Sample Number: 45775 Date: 7/21/20 Sample Number: 45710 Date: 7/21/20 Sample Number: 45602 Date: 7/21/20 Sample Number: 45530 5. An interview with the technical consultant (as indicated on the CMS 209 form, signed by the laboratory director on 9/29/20) on 10/7/20 at 11:20 a.m. in the office, after review of the records, 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 a review of the laboratory's records and staff interview, it was revealed the laboratory failed to have a quality assessment program that could identify and correct problems in analytic systems. Findings include: 1. The quality assessment program failed to identify that the laboratory did not have documentation of corrective actions when the room temperature was outside of the laboratory's acceptable range. (refer to D5781)