Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0861378	03/03/2021
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 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.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory test records from November 2020 to January 2021 and confirmed in interview with the technical consultant, the laboratory failed to follow the manufacturer's instructions when performing the BD Veritor System for the Rapid Detection of SARS-CoV-2 test. Findings were: 1. Review of the instructions for use for the EUA approved BD Veritor System for the Rapid Detection of SARS-CoV-2 (500048916(01) 2020-07) test under Conditions of Authorization for the Laboratory revealed "Authorized laboratories using your product will include with test results, all authorized Fact Sheets." 2. Random review of the patient testing from November 2020 to January 2021 revealed the laboratory performed the following 9 COVID testing without documentation of providing the Fact Sheet to the patient per the manufacturer's instructions. 11/09/20 - Patient ID 275879, Patient ID 281473, Patient ID 281456 11 /30/20 - Patient ID 250262 12/17/20 - Patient ID 281530 01/22/21 - Patient ID 283771 01/25/21 - Patient ID 279897, Patient ID 283799, Patient ID 283797 3. An interview with the technical consultant on 3/2/21 at 1135 hours in the office confirmed the

	above findings. She was unaware the laboratory was required to provide the Fact Sheet for Covid testing with the patient results.
D5461	CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory records from December 2020 to February 2021 and confirmed in interview, the laboratory failed to document a quality control run after a change in reagents on the Sysmex XN450 hematology analyzer for 2 of 7 days reviewed. Findings were: 1. Random review of the December 2020 to February 2021 Reagent Replacement log revealed the 2 of 7 days with no documentation of the quality control run after the following reagent change on the Sysmex XN450 hematology analyzer. 12/17/20 CellPack DCL lot Y0018, exp 2/21/22 12/22/20 Lysercell WDF lot Y0018, exp 2/3/21 2. Review of the patient test records for the above dates revealed the laboratory performed patient testing after the reagent change above with no documentation of the quality control run. 12/17/20 Patient ID 282455 12/22/20 Patient ID 75527, 254524, 62529, 259254 3. An interview with the technical consultant on 3/3/21 at 1120 hours in the office confirmed the above findings.
D5475	CONTROL PROCEDURES CFR(s): 493.1256(e)(3)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control records from 2020, laboratory patient records, and confirmed in interview with the technical consultant, the laboratory failed to document the positive and negative staining controls each day of testing for the flow cytometry testing on the Beckman Coulter Navios flow cytometer or provide an IQCP (Individualized Quality Control Plan) to reduce the frequency of the positive and negative staining controls to once monthly. Findings were: 1. Review of the laboratory records revealed the laboratory performed flow cytometry evaluating the following 29 markers: CD2 CD3 CD4 CD5 CD8 CD10 CD11b CD13 CD14 CD16 CD19 CD20 CD22 CD23 CD33 CD34 CD38 CD45 CD56 CD57 CD64 CD103 CD117 FMC7 HLA-DR Surface kappa Surface lambda 7-AAD 2. Random review of the laboratory quality control records from January 2020 to November 2020 revealed the laboratory performed positive and negative staining controls using the Streck CD Chex quality control monthly on 1/2/20, 10/20/20 and 11/20/20. 01/02/20: lot 93230041, exp 2/2/20 10/20/20: lot 02440041, exp 11/28/20 11/20/20: lot 02440041, exp 11/28/20 3. Random review of the laboratory patient records from January 2020

	to November 2020 revealed the laboratory performed 7 patient testing with no documentation of the daily positive and negative staining controls for the following days the laboratory performed patient testing. 01/07/20 - Patient ID 268165 01/09/20 - Patient ID 267883 01/14/20 - Patient ID 265323 01/29/20 - Patient ID 268506 10/28 /20 - Patient ID 279782 10/29/20 - Patient ID 280801 11/10/20 - Patient ID 276943 4. Review of the laboratory quality control records revealed no documentation of an IQCP (Individualized Quality Control Plan) to reduce the frequency of the positive and negative staining controls to once monthly. 5. An interview with the technical supervisor on 3/3/21 at 1130 hours in the office confirmed the above findings. key: CD2 - cluster of differentiation 2 CD3 - cluster of differentiation 3 CD4 - cluster of differentiation 4 CD5 - cluster of differentiation 5 CD8 - cluster of differentiation 8 CD10 - cluster of differentiation 10 CD11b - cluster of differentiation 11b CD13 - cluster of differentiation 13 CD14 - cluster of differentiation 14 CD16 - cluster of differentiation 16 CD19 - cluster of differentiation 19 CD20 - cluster of differentiation 20 CD22 - cluster of differentiation 22 CD23 - cluster of differentiation 23 CD33 - cluster of differentiation 33 CD34 -cluster of differentiation 34 CD38 -cluster of differentiation 38 CD45 - cluster of differentiation 45 CD56 - cluster of differentiation 56 CD57 - cluster of differentiation 57 CD64 - cluster of differentiation 64 CD103 - cluster of differentiation 103 CD117 -cluster of differentiation 117 FMC7 -epitope of CD20 HLA-DR - Human Leukocyte Antigen-antigen D Related 7-AAD - 7-aminoactinomycin D
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of the laboratory records from 2019 and 2020 and confirmed in interview with the technical consultant, the laboratory failed to monitor and evaluate twice yearly the CBC testing (complete blood count) on 2 of 2 Sysmex XN 450 hematology analyzers. Findings were: 1. Surveyor observations on a tour of the laboratory on 3/2/21 at 0910 revealed the laboratory had 2 Sysmex XN450 hematology analyzers: SN11698, SN11758 2. Random review of the laboratory records from 2019 and 2020 revealed the laboratory performed CBC testing using both Sysmex analyzers. 3. Review of the 2019 laboratory records revealed the laboratory performed a comparison assessment 1 of 2 times between the Sysmex analyzers. No documentation was available for review of the other comparison study. 4. Review of the 2020 laboratory records revealed no documentation of a comparison assessment between the Sysmex analyzers. 5. Review of the laboratory policies revealed no documentation of a policy or procedure to evaluate twice yearly the CBC testing using the different hematology instruments. 6. An interview with the technical consultant on 3/2/21 at 1245 hours in the office 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 the laboratory quality assessment records, review of quality control records, reagent logs, and confirmed in interview, the laboratory's quality assessment policies failed to monitor, assess, and correct problems in analytic systems. Refer to D5461, D5475, D5775