Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	45D0490471	09/25/2019
Name of Provider or Supplier	**Street Address, City, State**	
Oncology Consultants Pa	925 Gessner, Suite 600, 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	The laboratory was found out of compliance with the CLIA regulations. The condition not met was: D6063 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. 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.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Medical Laboratory Evaluation (MLE) proficiency testing records from 2018, and staff interview, it was revealed the laboratory failed to have documentation of the laboratory director signing 2 of 3 attestation statements. Findings include: 1. A review of the laboratory's Medical Laboratory Evaluation (MLE) proficiency testing records from 2018 revealed the laboratory failed to have documentation of the laboratory director signing the following 2 attestation statements: 2018 MLE- M2 2018 MLE- M3 Each attestation statement was signed by the technical consultant in the area designated for the laboratory director or designee to sign. 2. The laboratory was asked to provide

	documentation of the laboratory director delegating this responsibility to the technical consultant. No documentation was provided. 3. An interview with technical consultant (as indicated on the CMS 209 form, signed by the laboratory director on 9/23/19) on 9/25/19 at 9:40 a.m. in the conference room, after review of the records, confirmed the above findings.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on the laboratory's Medical Laboratory Evaluation (MLE) proficiency test results and staff interview, it was revealed the laboratory failed to attain a score of at least 80 percent for the analyte Hemoglobin for 2019 MLE-M1. Findings include: 1. A review of the laboratory's Medical Laboratory Evaluation (MLE) proficiency test results for 2019 MLE-M1 revealed the laboratory received a grade of unacceptable for 2 out of 5 samples, resulting in a 60 percent for the analyte Hemoglobin. The following results were submitted: Sample Reported Result Expected Results MX - 1 6.0 5.5 - 6.4 MX - 2 19.4 16.6 - 19.2 MX - 3 13.3 12.2 - 14.2 MX - 4 19.4 16.6 - 19.2 MX - 5 13.2 12.2 - 14.2 2. An interview with the technical consultant (as indicated on the CMS 209 form, signed by the laboratory director on 9/23/19) on 9/25/19 at 9:20 a.m. in the conference room confirmed the above findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate 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 verification records for the Sysmex XN 450 hematology analyzers, and staff interview, it was revealed the laboratory failed to have documentation of verifying it patient normal ranges prior to reporting patient test results. Findings include: 1. A review of the laboratory's policy titled "Reporting Results" revealed the laboratory listed the following for Adult Reference Ranges: WBC 3.8 - 11 RBC male: 4.5 - 6.1 female: 4.1 - 5.4 HGB male: 13.5 - 18.0 female: 11.5 - 16.0 HCT male: 42 - 54 female: 37- -47 MCV 80 - 101 MCH male: 26.1 - 33.5 female: 26.5 - 33.5 MCHC male: 32.2 - 35.0 female: 31.9 - 35.5 RDW-CV male: 11 - 15 female: 10.5 - 14.5 MPV male: 6 - 10.0 female: 7.2 - 10.6 PLT 140 - 450 Neut% 48 - 80 Lymph% 20 - 48 Mono% 2 - 9.8 Eo% 0 - 5 Baso% male: 0 - 2 female: 0 - 5 Neut# 2.0 - 8.0 Lymph# 1.0 - 5.0 Mono# 2 - 9.8 Eo# 0.0 - 0.4 Baso# 0.0 - 0.2 2. A review of the laboratory's verification records for the Sysmex XN 450 hematology analyzers revealed the following analyzers and their installation dates: Sysmex XN 450 SN: 11693 install date: 9/2018 Sysmex XN

	450 SN: 11773 install date: 1/2019 3. A review of the laboratory's verification records for the Sysmex XN 450 hematology analyzers revealed the laboratory failed to have documentation of verifying its patient normal ranges for the following tests: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, MPV, PLT, Neut %, Lymph %, Mono %, Eos%, Baso %, IG%, Neut, Lymph, Mono, Eos, Baso, IG 4. The laboratory was asked to provide documentation of verifying the identified patient normal ranges. No documentation was provided. 5. An interview with technical consultant (as indicated on the CMS 209 form, signed by the laboratory director on 9 /23/19) on 09/25/19 at 11:00 a.m. in the conference room revealed the laboratory did not verify its patient normal ranges for CBC testing. This confirmed the above findings. Key: SN - serial number WBC - white blood cell RBC - red blood cell HGB - hemoglobin HCT - hematocrit MCV - mean corpuscular volume MCH - mean corpuscular hemoglobin MCHC- mean corpuscular hemoglobin concentration RDW- red cell distribution width MPV - mean platelet volume PLT - platelet Neut % - percent neutrophils Lymph % - percent lymphocytes Mono % - percent monocytes Eos % - percent eosinophils Baso % - percent basophils IG % - percent immature granulocytes Neut # - number neutrophils Lymph # - number lymphocytes Mono # - number monocytes Eos # - number eosinophils Baso # - number basophils IG # - number immature granulocytes CBC - complete blood count
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the manufacturer's Quick Guide for the Sysmex XN 450 hematology analyzer, a review of the laboratory's maintenance records for the Sysmex XN 450 hematology analyzers from December 2018 - August 2019, and staff interview it was revealed the laboratory failed to have documentation of performing the required weekly maintenance. Findings include: 1. A review of the manufacturer's Quick Guide for the Sysmex XN 450 hematology analyzer (Document Number 1230-CFL REV. 2, 11/2017) revealed the following maintenance was required to be performed weekly: -Routine Cleaning 2. A review of the laboratory's maintenance records for the Sysmex XN 450 hematology analyzers revealed the laboratory had 2 analyzers: Sysmex Serial Number: 11693 Sysmex Serial Number: 11773 3. Further review of the laboratory's maintenance records for the Sysmex XN 450 hematology analyzers from December 2018 - August 2019 revealed the laboratory failed to have documentation of performing the following required weekly maintenance: Sysmex XN 450 Serial Number 11693: - December 2018 (1 of 4 weeks not documented) week of December 3rd - April 2019 (1 of 4 weeks not documented) week of April 22nd - May 2019 (1 of 4 weeks not documented) week of May 6th - June 2019 (1 of 4 weeks not documented) week of June 24th - August 2019 (2 of 4 weeks not documented) week of August 19th week of August 26th Sysmex SN 450 Serial Number 11773: - April 2019 (4 of 4 weeks not documented) week of April 1st week of April 8th week of April 15th week of April 22nd - May 2019 (4 of 4 weeks not documented) week of May 6th week of May 13th week of May 20th week of May 27th -June 2019 (3 of 4 weeks not documented) week of June 3rd week of June 17th week of June 24th - July 2019 (1 of 4 weeks not documented) week of July 22nd 4. An interview with the technical consultant (as indicated on the CMS 209 form, signed by the laboratory

	director on 9/23/19) on 9/25/19 at 11:20 a.m. in the conference room, after review of the records, confirmed the above findings.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, a review of the laboratory's patient reports, and staff interview, it was revealed the laboratory failed to ensure the reference intervals it provides to its clients are accurate. Findings include: 1. A review of the laboratory's 'Reporting Results' policy revealed the laboratory established the following hematology testing adult reference ranges: WBC 3.8 - 11 RBC male: 4.5 - 6.1 female: 4.1 - 5.4 HGB male: 13.5 - 18.0 female: 11.5 - 16.0 HCT male: 42 - 54 female: 37- -47 MCV 80 - 101 MCH male: 26.1 - 33.5 female: 26.5 - 33.5 MCHC male: 32.2 - 35.0 female: 31.9 - 35.5 RDW-CV male: 11 - 15 female: 10.5 - 14.5 MPV male: 6 - 10.0 female: 7.2 - 10.6 PLT 140 - 450 Neut% 48 - 80 Lymph% 20 - 48 Mono% 2 - 9.8 Eo% 0 - 5 Baso% male: 0 - 2 female: 0 - 5 Neut# 2.0 - 8.0 Lymph# 1.0 - 5.0 Mono# 2 - 9.8 Eo# 0.0 - 0.4 Baso# 0.0 - 0.2 2. A review of the laboratory's patient reports revealed the following reference intervals were listed for both male and female patients for hematology testing: WBC 3.80 - 11.00 RBC 4.10 - 6.10 HGB 11.5 - 18.0 HCT 37.0 - 54.0 MCV 80.0 - 101.0 MCH 26.1 - 33.5 MCHC 31.9 - 35.5 RDW-CV 10.5 - 15.0 MPV 6 - 10.0 PLT 140 - 450 Neut% 48 - 80 Lymph% 20 - 48 Mono% 2 - 9.8 Eo% 0 - 5 Baso% 0 - 5 Neut# 2.0 - 8.0 Lymph# 1.0 - 5.0 Mono# 0.1 - 1.0 Eo# 0.0 - 0.4 Baso# 0.0 - 0.2 3. Further review of the reference intervals listed on the laboratory's patient reports revealed the reports do not include separate ranges for male /female as indicated in the laboratory's policy for the following analytes: RBC HGB HCT MCH MCHC RDW- CV MPV Baso% 4. An interview with the technical consultant (as indicated on the CMS 209 form, signed by the laboratory director on 9 /23/19) on 9/25/19 at 11:30 a.m. in the conference room, after review of the records, confirmed the above findings. Key: WBC - white blood cell RBC - red blood cell HGB - hemoglobin HCT - hematocrit MCV - mean corpuscular volume MCH - mean corpuscular hemoglobin MCHC- mean corpuscular hemoglobin concentration RDW- red cell distribution width MPV - mean platelet volume PLT - platelet Neut % - percent neutrophils Lymph % - percent lymphocytes Mono % - percent monocytes Eo % - percent eosinophils Baso % - percent basophils Neut # - number neutrophils Lymph # - number lymphocytes Mono # - number monocytes Eo # - number eosinophils Baso # - number basophils
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, review of the Medical Laboratory Evaluation (MLE) proficiency testing results for 2018 and 2019, and staff interview, it was revealed the laboratory director failed to ensure the laboratory was following its policy for performing corrective actions on proficiency testing results scoring less than 100 percent. Findings include: 1. A review of the laboratory's policy titled "Proficiency Testing" revealed the following: "Proficiency samples must be kept and refrigerated until the results come back from MLE. If the results are not 100% corrective actions must take place on the retained samples, by re-running and comparing the results to the references ranges given by the proficiency company." 2. A review of the laboratory's Medical Laboratory Evaluation (MLE) proficiency testing results for 2018 and 2019 revealed the following results where the score was less than 100% and no corrective action was documented: 2018 MLE - M3: Monocytes Analyte Score: 92% 2019 MLE - M1: Red Blood Cell Count Analyte Score: 80% Hemoglobin Analyte Score: 60% Hematocrit Analyte Score: 80% 3. The laboratory was asked to provide documentation of repeating the tests as required by its policy. No documentation was provided. 4. An interview with the technical consultant (as indicated on the CMS 209 form, signed by the laboratory director on 9/23/19) on 9 /25/19 at 9:40 a.m. in conference room, after review of the records, confirmed the above findings.
D6054	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 at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted CMS 209 form, review of the laboratory's personnel files, and staff interview, it was revealed the technical consultant failed to perform a competency assessment in 2018 on 8 of 11 testing personnel for moderate complexity testing. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 9/23/19), revealed the laboratory identified 11 testing personnel. 2. A review of the laboratory's personnel records revealed that there was no documentation of the technical consultant performing a competency assessment in 2018 for the following testing personnel: Testing person #2 Testing person #3 Testing person #5 Testing person #7 Testing person #8 Testing person #9 Testing person #10 Testing person #11 3. An interview with the technical consultant (as indicated on the CMS 209 form) on 9/25 /19 at 10:20 a.m. in the conference room revealed, after review of the records, confirmed the above findings.
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 a review of the laboratory's installation records for the Sysmex XN 450 hematology analyzers, a review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant assessing competency of testing personnel before testing patient samples after new instrumentation was installed. Findings include: 1. A review of the laboratory's installation records for the Sysmex XN 450 hematology analyzers revealed the laboratory installed new instruments and started performing testing at the following time: -Sysmex XN 450 Serial Number 11693 Install date: 9/2018 -Sysmex XN 450 Serial Number 11773 Install date: 1/2019 2. A review of the laboratory's personnel records revealed the following testing personnel (as indicated on the CMS 209 forms, signed by the laboratory director on 9/23/19) failed to have documentation of competency assessments being performed prior to patient testing: - Testing Person #1 Competency assessed 9/6/19 - Testing Person #2 Competency assessed 9/6/19 - Testing Person #3 Competency assessed 9/6/19 - Testing Person #4 Competency assessed 1/22/19 - Testing Person #5 No documentation of a competency assessment for 2018 or 2019 - Testing Person #6 Competency assessed 9/6/19 - Testing Person #7 Competency assessed 9/6/19 - Testing Person #8 Competency assessed 9/6/19 - Testing Person #9 Competency assessed 9/6/19 - Testing Person #10 No documentation of a competency assessment for 2018 or 2019 3. The laboratory was asked to provide documentation of the technical consultant performing competency assessments prior to the identified testing personnel performing patient testing. No documentation was provided. 4. An interview with the technical consultant on 9/25/19 at 10:20 a.m. in the conference room, after review of the records, confirmed the above findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on a review of the laboratory's personnel records and staff interview it was revealed the laboratory failed to ensure testing personnel were qualified. Findings include: 1. The laboratory failed to ensure 2 of 11 testing personnel had documentation of education to qualify to perform moderately complex testing (refer to D6065). 2. The laboratory failed to have documentation of training for 3 of 11 testing personnel for the Sysmex XN 450 hematology analyzer (refer to D6066).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a

	chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on a review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of the education for 2 of 11 testing personnel in order to qualify them to perform moderate complexity testing. Findings include: 1. A review of the CMS 209 form (signed by the laboratory director on 9/23/19) revealed 11 testing personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of the education for 2 of 11 testing personnel. The testing personnel missing the documentation of education: Testing Person #5 Testing Person #10 3. The laboratory was asked to provide the documentation of education. No documentation was provided. 4. An interview with the technical consultant (as indicated on the CMS 209 form) on 9/25/19 at 12:00 p.m. in the conference room revealed the laboratory did not have documentation of education for testing person #5 or testing person #10. This confirmed the above findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of training for 3 of 11 testing personnel for the Sysmex XN 450 hematology analyzer. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 9/23/19) revealed the laboratory identified 11 testing personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel files revealed the laboratory failed to have documentation of training for hematology testing on the Sysmex XN 450 analyzer for 3 of 11 testing personnel. The following testing personnel were missing documentation of training: Testing Person #2 Testing Person #3 Testing Person #8 3. The laboratory was asked to provide documentation of training. No documentation was provided. 4. An interview with the technical consultant (as indicated on the CMS 209 form) on 9/25/19 at 10:00 a.m. in the conference room, after review of the records, confirmed the above findings.