Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2216344	10/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Usmd Red Bird Square Oncology And Infusion Center	3107 West Camp Wisdom Rd Suite 110, Dallas, 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: D6033 - 42 C.F.R. 493.1409 Condition: technical consultant 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.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's verification records for the Sysmex XN-430 hematology analyzer and staff interview, it was revealed the laboratory failed to have documentation of retaining instrument printouts or results used to assess instrument accuracy. The findings include: 1. A review of the laboratory's verification records for the Sysmex XN-430 hematology analyzer (serial number 11485) performed in March 2021 revealed the laboratory assessed instrument accuracy by performing instrument comparisons of CBC (complete blood count) results to results obtained from another facility. The laboratory failed to have documentation of the instrument printouts or results from the other facility for review as part of the verification studies. 2. The laboratory was asked to provide documentation of the instrument printouts or results from the other facility for review. No documentation was provided. 3. An interview with the technical consultant on 10/25/2022 at 1011 hours in the break room revealed the laboratory did not have the instrument printouts or results from the other facility. This confirmed the findings.

D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, review of the laboratory's policies, and staff interview, it was revealed the facility failed to have documentation of a policy which defined the requirements for competency assessments of the technical consultant. The findings include: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 10/25/2022) revealed the laboratory identified 1 technical consultant. 2. A review of the laboratory's personnel records revealed a competency assessment was performed on the technical consultant in March 2021 by someone other than the laboratory director. It was performed by the Senior Director of Laboratory Services for the facility. 3. A review of the laboratory's policies revealed the facility failed to have documentation of a policy to define the requirements for competency assessments of consultants (clinical and technical). 4. The laboratory was asked to provide documentation of a policy. No documentation was provided. 5. An interview with the technical consultant on 10/25/2022 at 0930 hours in the break room revealed the facility was unaware it needed a policy. This confirmed the findings.
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 the manufacturer's instructions for the Sysmex XN-430 hematology analyzer, review of the laboratory's policies, review of patient test records from October 2022, and staff interview, it was revealed the laboratory failed to have documentation of a policy to ensure corrective actions were performed on 7 of 25 CBC (complete blood count) results. The findings include: 1. A review of the

	manufacturer's instructions for the Sysmex XN-430 hematology analyzer (Code No. 12660 en-am, revision date: 08/2019) under the section titled "5.1 Overview of IP Messages" revealed: "When analysis data is analyzed, information that supplements the Positive/Negative sample judgment appears in the [Data Browser] screen. Results without an analysis error are classified as Positive or Negative based on preset criteria. The system judges flags for analysis data based on comprehensive surveys of numerical data, distributions, and scattergrams, and provides easy-to-understand messages indicating the results. These messages are referred to as "IP (interpretive Program) messages"." And, "Caution! A Positive or Error judgment indicate the possibility of an abnormality. It is not a diagnosis of the patient. If a Positive or Error judgment occurs, check the data and repeat the analysis, or examine carefully in accordance with the protocol of your laboratory. IP messages are only intended for use in the clinical laboratory and are not for patient diagnosis. IP messages provide notification of the possibility of a specific sample abnormality based on examination of the analysis data." 2. A review of the laboratory's policies revealed the facility did not have documentation of a policy defining the steps to follow when Positive judgments and/or IP messages were provided on patient results. 3. A sampling of patient test records from 10/18/2022 to 10/24/2022 identified 7 of 25 patient results which were identified as "Positive" and/or had IP messages identified. They were: a) Patient ID: 2432139 Test date: 10/19/2022 Positive Morphology IP messages: Anisocytosis Plt Abn Distribution b) Patient ID: 2392022 Test date: 10/19/2022 Positive Morphology Count IP messages: Anisocytosis Plt Abn Distribution Thrombocytopenia c) Patient ID: 2395349 Test date: 10/20/2022 Positive Morphology IP messages: Anisocytosis Hypochromia Addition messages: Scan smear for abnormal morphology Scan for RBC morphology d) Patient: 2422424 Test date: 10 /21/2022 Positive Morphology IP messages: Plt Abn distribution Additional messages: review platelet count e) Patient: 2402990 Test date: 10/21/2022 Positive Differential Morphology Count IP messages: Neutropenia Lymphocytosis RBC Abn Distribution Dimorphic Distribution Thrombocytopenia Additional messages: Perform a manual diff Chk tube for clot/vol review plt count f) Patient: 2429639 Test date: 10/24/2022 Positive Count IP messages: Thrombocytopenia Additional messages: review plt count g) Patient: 2400747 Test date: 10/24/2022 Positive Differential IP messages: Neutropenia Lymphocytosis Additional messages: Perform manual diff 4. The laboratory was asked to provide documentation of evaluating the identified results and of having a policy for testing personnel to follow. No documentation was provided. 5. An interview with the technical consultant on 10/25 /2022 at 1245 hours in the break room revealed results from the analyzer - whether positive or with IP flags were sent to the laboratory's laboratory information system without review. This confirmed the findings. Key diff - differential plt - platelet Abn - abnormal RBC - red blood cell chk - check vol - volume
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 review of the laboratory's verification studies performed on the Sysmex XN-430 hematology analyzer, review of patient test reports, and staff interview, it was revealed the facility failed to have documentation of verifying patient normal ranges currently in use. The findings include: 1. A review of the laboratory's verification studies performed on the Sysmex XN-430 hematology analyzer (serial number 11465) in March 2021 revealed the facility failed to have documentation of verifying patient normal ranges for CBC (complete blood count) tests. 2. A review of patient test reports from October 2022 revealed the laboratory used the same reference ranges for both male and female patients. The reference ranges currently in use were: White Blood Cell 4.5 - 10.5 Red Blood Cell 3.86 - 5.16 Hemoglobin 11.7 - 15.7 Hematocrit 34.8 - 45.8 MCV 77 - 91 MCH 31.7 - 36 MCHC 25.7 - 31.5 Platelet 176 - 407 Neutrophils (%) 40 - 76 Lymphocytes (%) 20 - 47 Monocytes (%) 0 - 10 Eosinophils (%) 0 - 8 Basophils (%) 0 - 4 Neutrophils (#) 1.4 - 7 Lymphocytes (#) 0.7 - 3.1 Monocytes (#) 0.1 - 0.9 Eosinophils (#) 0 - 0.4 Basophils (#) 0 - 0.3 IG (%) none IG (#) none RDW none RDW Ratio 12.3 - 15.1 3. The laboratory was asked to provide documentation of verifying the identified reference ranges. No documentation was provided. 4. The laboratory reported performing 18,180 hematology tests annually. 5. An interview with the technical consultant on 10/25/2022 at 1017 hours in the break room revealed the facility did not have documentation of verifying the reference ranges currently in use. This confirmed the findings. Key MCV - mean corpuscular volume MCH - Mean corpuscular hemoglobin MCHC - Mean corpuscular hemoglobin concentration IG - immature granulocytes RDW - red cell distribution width
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records, review of the laboratory's policies, and staff interview, it was revealed the laboratory failed to have documentation of verifying 5 of 5 lots of hematology quality controls. The findings include: 1. A review of the laboratory's Sysmex XN-L Check quality control records from 2021 and 2022 revealed the laboratory placed the following 5 lots into use: Lot: 1184 Lot: 1268 Lot: 1352 Lot: 2071 Lot: 2155 2. The laboratory was asked to provide documentation of verifying the 5 control lots. No documentation was provided. 3. A review of the laboratory's policies revealed the facility failed to have documentation of a policy or procedure about performing verification of new lots of control material. 4. An interview with the technical consultant on 10/25/2022 at 1100 hours in the

	break room revealed the facility did not verify new lots of control material. This confirmed the findings.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 1 technical consultants (refer to D6035).
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 1 technical consultants. The findings include: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 10/25/2022) revealed the facility identified 1 technical consultant. 2. A review of the laboratory's personnel records revealed the technical consultant had a diploma for a Bachelor in Arts and Sciences, however the diploma did not identify the major. The records did not contain transcripts to determine with course of study. 3. The laboratory was asked to provide documentation of the major in which the technical consultant received his degree. No documentation was provided. 4. An interview with the technical consultant on 10/25/2022 at 0915 hours in the break room - after his review of the records- confirmed the 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 review of the laboratory's submitted Form CMS 209, review of patient test records, and staff interview, it was revealed the laboratory failed to have documentation of training for 2 of 2 testing personnel who performed testing on the Sysmex XN-460 hematology analyzer. The findings include: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 10/25 /2022) revealed the facility identified 2 testing personnel who performed testing on the Sysmex XN-460 hematology analyzer. 2. A review of the laboratory's personnel records revealed the facility failed to have documentation of training on the Sysmex XN-460 hematology analyzers for 2 of 2 testing personnel. They were (as listed on Form CMS 209): Testing personnel number 1 (hired: April 2021) Testing personnel number 2 (hired: April 2022) 3. The laboratory was asked to provide documentation of training. No documentation was provided. 4. An interview with the technical consultant on 10/25/2022 at 0920 hours in the break room - after his review of the records- confirmed the findings.