Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2218807	11/18/2022
Name of Provider or Supplier	**Street Address, City, State**	
Usmd Cleburne Oncology And Infusion Center	1301 West Henderson St Suite A, Cleburne, 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	An entrance conference was held with the laboratory representatives. The survey process was discussed, and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives 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 NOT in compliance with the CLIA conditions for specialties /subspecialties surveyed for 42 CFR 493.1409 Laboratories performing moderate complexity testing; technical consultant 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.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policy, patient test records, and confirmed in staff interview, the laboratory failed to follow the manufacturer's instructions to ensure accurate and reliable test results for specimens with instrument flags for 8 of 20 patient Complete Blood Counts (CBCs) tested on the Sysmex XN-430 hematology analyzer in November 2022. The findings include: 1. Review of the

	Sysmex XN-L Series XN-530/XN-430/XN-330 Troubleshooting Guide revealed: "5.1 Overview of IP messages ... Results without an analysis error are classified as Positive or Negative based on present criteria. The system judges flags for analysis data based on comprehensive surveys of numerical data, distributions and scattergrams, and provides easily-to-understand messages indicating the results. These messages are referred to as "IP (Interpretive Program) messages" ... Caution! -A Positive or Error judgement indicates the possibility of an abnormality. It is not a diagnosis of the patient. If a Positive or Error judgement 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 analysis data... Message types There are 2 types of IP messages that may be displaced for WBC, RBC/RET, and PLT: abnormal messages and suspect messages. Abnormal messages Indicates that the sample is clearly abnormal. With some exceptions, the criteria for abnormal message judgement can be preset. Suspect messages Indicates a possibility that the sample is abnormal. Positive /Negative judgement [Positive] Indicates that a blood cell analysis value or cell morphology exceeds the preset criteria for the IP message (abnormal sample)." 2. Review of the 1. Review of the Sysmex XN-L Series XN-530/XN-430/XN-330 Basic Operation Guide revealed: "Chapter 5 Checking Analysis Results (Sample Explorer) ... Information -Flags (IP messages) are only intended for use in the clinical laboratory and are not for patient diagnosis. Flags notify the operator of the possibility of a specific sample abnormality that requires examination of the analysis results ..." 3. Review of the laboratory's policy titled "Sysmex XN 430 Analyzer" revealed no instructions for verification of results with flagged parameters. 4. Review of instrument printouts from the Sysmex XN-430 and final reports revealed the following 8 of 20 patient CBCs that were tested and reported with flags/IP messages and/or comments in November 2022: 11/09/2022 Sample No: 1586344 WBC IP Message: "IG Present" Comment: "#26 IG- Perform Man Diff; Path if seen", "#56: RBC- Scan smear for morph" 11/14/2022 Sample No: 2412650 Comment: "#17 WBC- Perform Manual Diff" Sample No: 2433865 Comment: "#56: RBC- Scan smear for morph" Sample No: 134823 RBC IP Messages: "RBC Abn Distribution", "Dimorphic Population" Comment: "#32: RBC- Scan Smear for morph" 11/15/2022 Sample No: 2110074 Comment: "#56: RBC- Scan smear for morph" 11/16/2022 Sample No: 2386549 WBC IP Message: "Blasts/Abn Lympho?", "Atypical Lympho?" Comment: "#4 Blast/Abn Lymph? Man Diff; Path if ind", "#28 IG*- Perform Man Diff; Path if ind", "#3 Atyp Lymph-Scn Smr; Diff" 11/17/2022 Sample No: 972159 WBC IP Message: "IG Present" Comment: "#26 IG- Perform Man Diff; Path if seen", "#17 WBC- Perform Manual Diff", "#23: Mono-Perform Man Diff" 11/18/2022 Sample No: 11177642 Comment: "#77: Plt Critical-Call Results", "78: Plt- Send for Path Review" The laboratory reported patient specimens with possible abnormal results. The laboratory failed to follow manufacturer's instructions to ensure accurate and reliable test results. 4. During an interview on 11/18/2022 at 12:45 p.m., the Senior Director of Laboratory Services and Technical Consultant confirmed the above findings. Key: WBC: White blood cell RBC: Red blood cell Man Diff: Manual Differential Path: Pathology review Morph: Morphology Mono: Monocyte IG: Immature granulocyte Abn: Abnormal Atyp: Atypical Lymph(o): Lymphocyte Ind: Indicated Scn Smr: Scan Smear Plt: platelet
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper

	storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the operator's guide, laboratory environmental logs, and confirmed in interview, the laboratory failed to monitor relative humidity for the Sysmex XN-430 hematology analyzer for 2 of 2 months in 2021 (November and December) and 11 of 11 months in 2022 (January to November). The findings include: 1. Review of the Sysmex XN-L Series XN-530/XN-430/XN-330 General Information guide revealed: "Performance Specifications/characteristics ... Operating Environment Ambient Temperature: 15 to 35C (also applies to supplied reagents) Relative Humidity: 20-85%..." 2. Review of the laboratory's environmental logs from November to December 2021 and January to November 2022 revealed no documentation of relative humidity for the Sysmex XN-430 hematology analyzer. The surveyor requested documentation of relative humidity for the Sysmex XN-430 hematology analyzer. None was provided. 3. During an interview on 11/18/2022 at 12: 08 p.m., the Senior Director of Laboratory Services and Technical Consultant confirmed the above findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation and confirmed in interview, the laboratory failed to ensure blood collection tubes did not exceed their expiration date. The findings include: 1. During a tour of the laboratory on 11/18/2022 at 12:37 p.m., the surveyor observed the following expired blood collections tubes in a cabinet: 1 package of 100 BD Vacutainer Buffered Sodium Citrate (9NC) Blood Collection Tubes; Lot # 1350271; Expiration: 2022-09-30 2. During an interview on 11/18/2022 at 12:37 p.m., the Senior Director of Laboratory Services and Technical Consultant confirmed the above 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 Centers for Medicare and Medicaid Services (CMS)- 209 form, laboratory personnel records, and confirmed in interview, the Technical

	Consultant (TC) failed to meet the qualification requirements for TC for a moderate complexity laboratory. 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 Centers for Medicare and Medicaid Services (CMS)- 209 form, laboratory personnel records, and confirmed in interview, the laboratory failed to ensure the Technical Consultant (TC) met the educational requirements to qualify as a TC for a moderate complexity laboratory. The findings include: 1. Review of the laboratory's CMS-209 form revealed 1 TC for the laboratory. 2. Review of the TC's personnel records revealed an Associates of Science in Medical Laboratory Technician and no documentation of any of the following education to qualify as TC for moderate complexity: -A current medical license and board certified or equivalent in anatomic or clinical pathology OR -MD or DO OR -Doctorate or master's degree in chemical, physical, biological, or clinical lab science OR -Bachelor's degree in chemical, physical, biological, or clinical lab science 3. During an interview on 11/18

	/2022 at 09:20 a.m., the Senior Director of Laboratory Services and Technical Consultant confirmed the above findings. Key: MD: Doctor of Medicine DO: Doctor of Osteopathic Medicine