Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1061372	07/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
Center For Cancer & Blood Disorders -	7415 Las Colinas Blvd Suite 100, Irving, 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 Choice Cancer Care Las Colinas clinical laboratory is not in compliance with the 42 CFR Part 493, Requirements for Laboratories. Biennial certification survey was conducted 07/19/19. Standard level deficiencies were cited as follows:
D2098	ENDOCRINOLOGY CFR(s): 493.843(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 API (American Proficiency Institute) proficiency testing results and interview with the Technical Consultant the laboratory failed to get at least 80% on 1 (1st testing event in 2018) out of 7 testing events (1st testing event 2019, 1st, 2nd, 3rd testing events 2018, and 1st, 2nd, 3rd testing events 2017) reviewed. Findings Included: Review of API proficiency testing results revealed a 60% in TSH (Thyroid Stimulating Hormone) in the 1st testing event in 2018. Interview on 07/19/19 at 3:00 PM the Technical Consultant confirmed the proficiency testing failures.
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 API (American Proficiency Institute) proficiency testing results and interview with the Technical Consultant the laboratory failed to get at least 80% on 2 (1st testing event 2019 and 1st testing event in 2018) out of 7 testing events (1st

	testing event 2019, 1st, 2nd, 3rd testing events 2018, and 1st, 2nd, 3rd testing events 2017) reviewed. Findings Included: Review of API proficiency testing results revealed a 0% in Basophils, Eosinophils, IG absolute, and IG percent in the 1st testing event in 2019. Review of API proficiency testing results revealed a 60% in Granulocytes, Hematocrit, Hemoglobin, Lymphocytes, MCH, MCV, Monocytes, Platelets, Red Cell Count, and White Cell Count in the 1st testing event in 2018. Interview on 07/19/19 at 3:00 PM the Technical Consultant confirmed the proficiency testing failures.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based record review and interview with the Technical Consultant the laboratory failed to verify the accuracy of the Cytology testing at least twice a year for 2 out of 2 years (2017-2018) reviewed. Findings Included: Review of policies and procedures (signed and dated as reviewed by the Laboratory Director on 07/17/19) revealed under peer review "Although the requirement is that two cases be peer reviewed twice a year, difficult or inconclusive cases will be reviewed on a prn basis. These will be chosen by the pathologist/Laboratory Director and/or Radiation Oncologist and reviewed by a board-certified pathologist. The reports will be filed in the Peer Review manual as well as the patient's EMR". Review of the Peer Review manual revealed peer reviews conducted on 11/21/17 and 01/18/18. Interview on 07/19/19 at 5:30 PM the Technical Consultant confirmed that there were no more peer reviews in Cytology for review.
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 record review and interview with the Technical Consultant the laboratory

	failed to have a complete procedure manual for Histopathology and Cytology for 2 out of 2 years (2017-2019) reviewed. Findings Included: Review of the policy and procedure manual for Histopathology and Cytology testing (last signed by the Laboratory Director as reviewed on 07/17/19) only had quality assurance, peer review, and chart review procedures in it. During an interview on 07/19/19 at 4:30 PM the Technical Consultant confirmed the policies and procedures for Histopathology and Cytology were not complete.