Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0154840	01/22/2018
Name of Provider or Supplier	**Street Address, City, State**	
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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
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 a surveyor's review of the laboratory policies and procedures and confirmed in an interview with the laboratory supervisor/testing person at the time of the survey, the laboratory failed to establish a comprehensive written policy and procedure that includes the six required components to assess testing personnel's competency annually. The six required components are: 1. direct observation of routine patient test performance, including preparation. specimen handling and testing; 2. monitoring the recording and reporting of test results; 3. review of intermediate results of worksheets, quality control records, proficiency testing results, and preventive maintenance records; 4. direct observation of performance of instrument maintenance and function checks; 5. assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and, 6. assessment of problem solving skills.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on the surveyor's review of Medical Laboratory Evaluation (MLE) Proficiency

	Testing (PT) reports and an interview with the laboratory supervisor/testing person, the laboratory failed to evaluate, perform and document remedial action for the PT scores of less than 100% for the following analytes in 2017. 2017 1st event: Thyroid Stimulating Hormone (TSH)= 60% 2017 3rd event: Hematocrit = 40% Red Blood Cells (RBC)= 60% White Blood Cells (WBC) = 80% Granulocytes = 93%
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's Quality Assessment (QA) policy /procedure and an interview, at the time of the onsite survey, with the laboratory supervisor/testing person, the laboratory failed to follow their established written QA policy and have a mechanism to monitor, assess and when indicated correct problems identified in the general laboratory system for chemistry, endocrinology and hematology testing, to prevent recurrence of the original problem.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a surveyor's review of hematology and endocrinology calibration records and interview with the laboratory supervisor/testing person, calibration of the hematology and endocrinology analyzers was not performed at the frequencies required by the laboratory's calibration protocol and by the manufacturer of the analyzers. FINDINGS: 1. The laboratory is using the Cell Dyn 1800 analyzer. The laboratory's calibration policy and the manufacturer of the hematology analyzer require analyzer calibration every six months. 2. The documentation of the Cell Dyn 1800 analyzer calibration available for review was for calibration performed on 7/8/15, 10/3/16, 4/20/17 and 10/23/17. The hematology analyzer was therefore out of calibration from 1/9/16 through 10/2/16 and from 4/4/17 through 4/19/17. 3. Approximately 500 patient specimens were tested and reported for hematology during the above time period when analyzer was out of calibration. 4. On January 22, 2018 at approximately 11:30 AM the laboratory supervisor/testing person confirmed that the records of calibration for the FREND System analyzer for TSH and FT4 testing for

	calendar year 2017 was not available for review. The only calibration record available was on 2/16/17 as part of validation study for the FREND analyzer. 5. Approximately 300 patient specimens were tested and reported for TSH and FT4 during the above time period.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor's review of the QC records, the FREND System manufacturer's operations manual and an interview with the laboratory supervisor/testing person, the laboratory failed to perform at least 2 levels of QC materials for TSH and FT4 on each day of testing. FINDINGS: 1. The laboratory supervisor/testing person confirmed on January 22, 2018 at approximately 11:30 AM, the laboratory failed to perform two levels of external QC prior to test patient samples for TSH and FT4 using the FREND System analyzer from February 2017 to survey date. The laboratory performs two levels of external QC once per month. 2. The QC procedure established by the laboratory indicates that the frequency of the external QC for TSH and FT4 to be reduced to once per month after completion of the Individualized Quality Control Program (IQCP). There was no record of IQCP available for review. 3. Approximately 300 patients were tested and reported for TSH and FT4 from February 2017 to survey date.
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 surveyor's review of Quality Control (QC) records and interview with the laboratory supervisor/testing person, the laboratory failed to program the manufacturer expected ranges, as defined on the QC assay sheets, into the Cell Dyn 1800 analyzer for the calendar year 2017. FINDINGS: 1. On January 22, 2018 at approximately 11:30 AM the laboratory supervisor/testing person confirmed the surveyor's review of QC records finding that the laboratory failed to program the established QC ranges and expected means accurately into the Cell Dyn 1800 analyzer for hematology tests performed. 2. Without the established QC limits the surveyor could not determine if the quality control results were within the acceptable ranges for the hematology analytes tested. 3. Approximately 500 patients' specimens were tested and reported for hematology during this time period.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor's findings and interview with the laboratory supervisor/testing person, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the laboratory: 1. maintained the laboratory's QC program for hematology and endocrinology; refer to D6020; 3. maintained the laboratory's established QA program by effectively identifying and correcting problems for all phases of laboratory testing, refer to D6021; and 4. performed annual competency evaluation for the testing personnel performing moderate complexity testing; refer to D6054.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a surveyor's review of QC records and confirmed in an interview with the laboratory supervisor/testing person at the time of this survey, the laboratory director failed to ensure that the QC program for hematology and endocrinology testing was maintained to assure the quality of laboratory services. Refer to: D5437, D5441, D5469
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor's review of the Quality Assessment (QA) review records and an interview with the laboratory supervisor/testing person, the laboratory director failed to ensure that the general laboratory systems QA reviews were performed monthly, as required by their QA policy, in calendar years 2016 and 2017. It was confirmed with the laboratory supervisor/testing person on the day of the survey at approximately 11: 30 AM that although the QA review records were available, the QA reviews failed to identify and address failures in proficiency testing, QC and calibration issues to prevent recurrence of the original failures and to assure the quality of laboratory services and compliance. Refer to D5291, D5211
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 a surveyor's review of the laboratory's personnel records and confirmed in an interview with the laboratory supervisor/testing person at the time of the survey, the laboratory director, acting as the technical consultant, failed to perform annual competency evaluation for the three of three testing persons. A form entitled Personnel Evaluation failed to assess competency in hematology, endocrinology and chemistry testing. The form was a character evaluation consisting of assessment of non-laboratory related standards (i.e., attitude, initiative, attendance). The form did not address specific laboratory skills. Refer to D5209