Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D0678969	09/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Thyroid And Diabetes Mgmt Ctr	8939 Broadway, Merrillville, IN	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on document review and interview, the laboratory failed to: 1) test proficiency (PT) samples in in the same manner as patient specimens (Refer to D2006); and 2) enroll in a PT program for the specialty of hematology and subspecialty of endocrinology for three of five PT testing events reviewed (Event 1 and 2, 2017 and Event 1, 2018). Findings include: 1. Review of laboratory director job description indicated the laboratory director was responsible to "...ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed in the laboratory." 2. Review of PT documents indicated PT testing was not performed for the speciality of hematology and subspecialty of endocrinology for testing events 1 and 2 of 2017 and event 1 of 2018. 3. Review of "Quality System Assessment Review" documents read: "Proficiency tests: checked for proper enrollment at renewal date..." and indicated the following: a. Report for "April - June 2017," dated "June 17," and initialed by the laboratory director, read: "API paid due fees...will start proficiency remaining of 2017..." b. Report for "Jan - March 2018," dated 3-30-2018 and initialed by the laboratory director, read: "Jan 2018 still waiting for PT enrollment..." 4. In interview on 9-5-2018 at 10:38 AM, SP3 indicated the laboratory did not enroll in a PT program for testing event 1, 2017. At 11:24 AM, SP3

	acknowledged the lab was not enrolled in a PT program during testing event 2, 2017. On the same date at 12:06 PM, SP1 indicated the laboratory did not enroll in a PT program for testing event 1, 2018.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to test proficiency (PT) samples in the specialty of hematology in the same manner as it tests patient specimens for two of two PT events reviewed. Findings include: 1. Review of policy /procedure titled: "Proficiency Testing," effective date unknown, read "Samples are treated and tested in the identical manner as a patient sample would be..." 2. Review of "Laboratory Personnel Report (CLIA)" form (CMS209), signed by the Laboratory Director on 9-5-2018, indicated SP3, SP4, and SP5 were testing personnel. 3. Review of proficiency testing attestation statements for the speciality of hematology during event 3, 2017 and event, 2, 2018 indicated PT was performed by SP3. These were the only hematology PT events performed in 2017 and 2018 (Refer to D2000). 4. Review of "Quality Systems Assessment Review" read: "Proficiency Tests...all lab staff participate..." and indicated there were no issues with all laboratory staff participating in proficiency testing activities for "April - June 2018," report dated 6-20-2018 and initialed by the laboratory director. 5. In interview on 9-5-2018 at 2:06 PM, SP2 indicated all hematology testing is performed by SP4 and SP5. 6. In interview on 9-5-2018 at 2:06 PM, SP3 indicated the only person who performs PT testing is SP3.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on document review and interview, the laboratory failed to: 1) retain analyzer printouts for at least two years (refer to D3031); and 2) ensure patient test reports were retrievable for at least two years after the date of reporting (refer to D3041).

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 document review and interview, the laboratory failed to retain analyzer printouts for at least two years for ten of ten patient test records requested. Findings include: 1. Review of policy / procedure titled: "Instrument Printouts," effective date unknown, read: "Printouts will be kept for two years." 2. Upon request for ten patient test records on 9-5-2018 at 11:57 AM, one patient test record (PT2) was provided. The provided record did not include an analyzer printout, but included a "Laboratory Flow Sheet," which included handwritten results in the column for 2-12-2018. 3. In interview on 9-5-2018, at 2:00 PM, SP1 acknowledged the laboratory did not have an analyzer printout for PT2. SP1 indicated the date on the "Laboratory Flow Sheet" of 2-12-2018 for PT2 was the test order date and not the date the test was performed. SP1 further indicated the laboratory did not have analyzer printouts for the other nine patient test records requested.
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure nine of ten requested patient test reports were retrievable for at least two years after the date of reporting. Findings include: 1. A certified letter, dated 7-17-2018 and received by the laboratory on 7-24-2018, indicated the laboratory's survey date would be on 9-5-2018 at 10:30 AM. 2. In a phone interview on 8-22-2018 at 12:19 PM, SP1 indicated the survey letter and packet of information was received by SP1 and SP1 did not have any questions. 3. On 9-5-2018 at 11:57 AM, a list of the following ten patient test reports was requested from SP1. Patient # Collection Date _____ TP1 2-27-2018 TP2 2-12-2018 TP3 3-22-2018 TP4 4-19-2018 TP5 5-31-2018 TP6 8-20-2018 TP7 7-23-2018 TP8 6-26-2018 TP9 5-21-2018 TP10 4-24-2018 4. In interview on 9-5-2018 at 11:57 AM, SP1 indicated the cabinet where patient test reports were maintained was locked and nine of the ten requested records were unable to be retrieved (TP1 and TP3 through TP10). The surveyors offered to exit the facility for an hour lunch to allow the facility time to unlock the cabinet. SP1 indicated the laboratory wished to continue the survey, as they would not be able to unlock the cabinet. SP1 further indicated patient test reports were unavailable at the time of survey.
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 document review and interview, the laboratory failed to ensure maintenance was performed with the frequency specified by the manufacturer for one of two analyzers reviewed. Findings include: 1. Review of "Operator's Manual" for the "Immulite 1000" analyzer indicated the following: a. Weekly maintenance included "cleaning the instrument fan filter" and "cleaning the computer fan filter." b. The water bottle was to be cleaned every two weeks. c. Monthly maintenance included "replacing the substrate spike," "changing the small syringe tip, and "Testing the water supply," 2. Review of Immulite 1000 maintenance records from February, 2018 to August, 2018 indicated the following: a. Required weekly maintenance was not performed on week 4 in March, April, May, June, and August. b. Required maintenance every two weeks was not performed in February and July. c. Required maintenance every two weeks was performed once in March (on 3-27-2018) and June (on 6-29-2018). d. Required monthly maintenance was not performed as follows: 1. The substrate spike was not changed in February. 2. The small syringe tip was not changed in February. 3. The water supply was not tested in February, March, April, and June. 3. In interview on 9-5-2018 at 10:54 AM, SP3 acknowledge the above maintenance, required by the manufacturer, was not performed.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory director failed to follow established policies and procedures for monitoring the competency of one of one testing personnel performing endocrinology testing. Findings include: 1. Review of "Laboratory Personnel Report (CLIA)" form (CMS209), signed by the laboratory director on 9-5-2018, indicated SP3 was a testing person. 2. Review of policy /procedure titled: "Employee Competency," effective date unknown, read: "It is the laboratory director's responsibility to determine if and when an employee is competent to perform patient sample testing (done twice during the first year, annually thereafter.)..." 3. Review of the Laboratory Director's job description read: "Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and post analytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently..." 4. Review of personnel

	records indicated SP3 had a "Detailed Training Checklist" dated 4-4-2017 for the moderately complex endocrinology tests performed on the Immulite 1000 analyzer. There was no documentation of a competency assessment twice in the first year after training. 5. In interview on 9-5-2018 at 10:25 AM, SP3 indicated there was no competency documentation for the moderate complexity endocrinology tests performed on the Immulite 1000 analyzer.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory director failed to ensure the quality assessment program identified the following failures: 1) the ability to retrieve nine of ten patient records requested; 2) record retention for ten of ten patient records; and 3) analyzer maintenance for one of two analyzers reviewed (Immulite 1000). Findings include: 1. Review of "Quality Systems Assessment Review" read: "Reports...available upon request..." and indicated the following: a. Report for "Jan - March 2018," dated 3-30-2018 and initialed by the laboratory director, indicated a quality assessment review of "reports" was "NA." b. Report for "April - June 2018," dated 6-20-2018 and initialed by the laboratory director, indicated a quality assessment review of "reports" was "NA." c. Report for "July - Sept 2018," dated 9-5-2018 and initialed by the laboratory director, indicated a quality assessment review of "reports" was not performed. 2. In interview on 9-5-2018 at 11:57 AM, SP1 indicated the laboratory was unable to retrieve patient test report for patient TP1 and patients TP3 through TP10 (Refer to D3041). 3. In interview on 9-5-2018, at 2:00 PM, SP1 acknowledged the laboratory did not have an analyzer printout for PT2. SP1 indicated the date on the "Laboratory Flow Sheet" of 2-12-2018 for PT2 was the test order date and not the date the test was performed. SP1 further indicated the laboratory did not have analyzer printouts for the other nine patient test records requested (Refer to D3031). 4. Review of "Quality System Assessment Review" read: "Maintenance: list each instrument, check for compliance with manufacturer requirements and documentation" and indicated the following: a. Report for "Jan - March 2018," dated 3-30-2018, and initialed by the laboratory director, indicated maintenance for that period was "ok." b. Report for "April - June 2018," dated 6-20-2018, and initialed by the laboratory director, indicated maintenance for that period was "ok...up to date." c. Report for "July - Sept 2018," dated 9-5-2018, and initialed by the laboratory director, indicated maintenance for that period was "ok." 5. Review of Immulite 1000 maintenance records from February 2018 to August 2018 indicated weekly, biweekly, and monthly maintenance was not performed as required by the manufacture (Refer to D 5429).