

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0214044	(X3) Date Survey Completed 12/13/2018
Name of Provider or Supplier Faith Hackett Md/Jeffrey Schmidlein Md	Street Address, City, State 844 Ritchie Highway Suite 206, Severna Park, MD	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records and interview with the testing person, the laboratory did not ensure that the all PT records were signed by the appropriate testing personnel as required. Findings: 1. The PT records from 2017 through 2018 (6 events) were reviewed. 2. According to the testing personnel the three physicians in the practice will evaluate all the patient and PT throat cultures interpretations prior to reporting the test results. 3. Review of the PT records showed that the 2nd and 3rd events of 2018 had not been initialed by the testing personnel. 3. Review of the PT records showed that all six events had not been initialed by the physician that had performed the final interpretation of the PT results. 4. During the survey on 12/13/2018 at 11:30 AM the testing person confirmed that the PT records were not being signed by all the appropriate laboratory staff.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p>

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 testing person, the laboratory did not have written policies and procedures for entering the final patient test result into the laboratory information system (LIS). Findings: 1. According to the testing person once the throat cultures are completed and documented on the worksheet the results are then entered into the LIS. 2. Review of the procedure manuals showed that there were no written policies and procedures for entering patient test results into the LIS. 3. During the survey on 12/13/18 at 11:30 AM the testing person confirmed that there were no detailed instructions for entering the patient test results into the LIS.

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 review of the evaluation documents, the laboratory director did not ensure that the policies for monitoring the laboratory staff included the technical consultant on an annual basis. Findings: Review of the evaluation documentation for 2017 and 2018 showed that there were no records showing that the competency of the technical consultant had been performed for 2017 and 2018.

D6022

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 and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of the laboratory records and interview with the testing personnel, the laboratory director did not ensure that the technical consultant (TC) performed a regular review of the laboratory worksheets, quality control (QC) records, temperature charts and maintenance records. Findings: 1. The quality assurance (QA) plan and the duties and responsibilities of the technical consultant failed to address the frequency of visits and reviews to be performed by the TC. 2. The TC confirmed that monthly visits were not being performed to review the laboratory's records. The monthly QC worksheets for 2017 and 2018 were not dated by the TC so there was no way to determine when the TC visited the laboratory. 3. During the exit interview on 12/13/18 at 11:30 AM the TC confirmed that reviews of the laboratory worksheets, QC temperature charts and maintenance records were not being performed in a timely manner and the data was not being reviewed with the laboratory director.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of the procedure manual and interview with the testing person, the laboratory director did not specify in writing, the responsibilities and duties of each person engaged in the performance of the pre-analytic, analytic and post analytic phases of testing, that identifies which examination and procedure each individual is authorized to perform, and whether supervisory or director review is required prior to reporting patient test results. Findings: During the survey on 12/13/18 at 11:30 AM the testing person confirmed that the laboratory's procedure manual did not specify in writing the duties and responsibilities of the laboratory testing personnel.

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 records, the Laboratory Personnel Report (CLIA) (Form CMS-209), and interview with the technical consultant, the laboratory did not ensure that the credentials for technical consultant were available at the time of the survey. Findings: 1. Form CMS-209 signed by the Laboratory Director on December 13, 2018 certifies that all the laboratory staff are qualified to hold the identified positions in the laboratory. 2. There were no credentials available at the time of the survey to show that the technical consultant meet the minimum educational requirement for technical consultant, e.g., a bachelor's degree and 2 years documented experience. 3. During the survey on 12/13/18 at 11:30 AM the technical consultant confirmed that the education credentials were not available at the time of the survey.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on review of the competency documentation and interview with the technical consultant (TC), the TC did not perform and document the competency review on all testing personnel. Findings: 1. The laboratory currently has 10 testing personnel listed on the "Laboratory Personnel Report (CLIA) (CMS-209)". 2. The annual competencies for 2017 and 2018 were reviewed for the testing personnel listed on the

CMS-209. The worksheets did not identify who had performed the evaluations. The lead testing person stated that she had performed the evaluations. 3. Review of the credentials of the lead testing person showed that she was not qualified with a Bachelor of Science with two years' experience. 4. The TC confirmed that the competency evaluations were initially performed by the lead testing person instead to the TC as required. 5. During the survey on 12/13/18 at 11:30 AM the TC confirmed that the evaluations for 2017 and 2018 were not performed by the qualified TC (Bachelor of Science with two years' experience).

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:
Based on review of the monthly quality control (QC) summaries provided by the technical consultant (TC) and interview with the TC, the TC did not include the date that the reviews were performed. Findings: 1. The monthly QC summaries for 2017 and 2018 showed that a review was performed each month but there was no date listed showing when the review was performed. The monthly summaries did not include a documented follow-up with the testing personnel and laboratory director when problems occurred. 2. The TC stated that she did not visit the laboratory on a monthly basis to review the QC data. The reviews were performed when she visited the laboratory. 3. During the survey on 12/13/18 at 11:30 AM the TC confirmed that the monthly QC reviews were not performed on a monthly basis to ensure that when problems occurred the testing personnel and laboratory director were informed in a timely manner to ensure the accuracy and reliability of the patient test results.