

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2145564	(X3) Date Survey Completed 07/23/2019
Name of Provider or Supplier Hamilton Physician Group - Catoosa Campus	Street Address, City, State 45 College Park Drive, Suite A, Ringgold, GA	
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 initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on July 23, 2019. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to establish a policy and procedure for specimen retention as required Findings include: 1. SOP review revealed the laboratory SOP did</p>

	<p>not include a policy and procedure for specimen retention. 2. An interview in the conference room with Staff #1 (CMS 209) on 7/23/2019 at approximately 12:30 p.m. confirmed there was not a policy and procedure in the laboratory SOP for specimen retention.</p>
<p>D5429</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on maintenance document review and staff interview, the laboratory failed to perform and document required equipment maintenance. Findings include: 1. Equipment maintenance log review revealed the eyewash equipment was not performed for the following months: 2018 - June through December; 2019 -- January through July (except for 7/11/2019). 2. An interview with Staff #1 (CMS 209) in the conference room at approximately 12:30 p.m. on 7/23/2019 confirmed the lack of eyewash maintenance for 2018 and 2019 thus far..</p>
<p>D6004</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</p> <p>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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappropriates performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the laboratory director (LD) failed to delegate technical consultant (TC) duties and responsibilities to qualified testing personnel (TP) as required. Findings include: 1. TP competency document review revealed the initial and six-month competencies for Staff #1 (CMS 209) were performed by an unqualified individual due to lack of education qualifications,. 2. TP competency document review revealed the six-month competency for Staff #2 (CMS 209) was performed by unqualified TP due to lack of education qualifications. 3. An interview with Staff #1 (CMS 209) in a conference room on 7/23/2019 at approximately 12:30 p.m. confirmed the aforementioned TP competencies was performed by unqualified TP/individuals due to lack of education qualifications.</p>
<p>D6029</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>The laboratory director is responsible for the overall operation and administration of</p>

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on testing personnel (TP) document review and staff interview, the laboratory director (LD) failed to ensure that, prior to testing patient's specimens, all TP have the appropriate training as required. Findings include: 1. TP document review revealed Staff #2 (CMS 209) did not have an initial competency performed in 2019. 2. An interview with Staff #1 (CMS 209) in a conference room on 7/23/2019 at approximately 12:30 p.m. confirmed there was no initial competency performed for Staff #2 (CMS 209) in 2019.

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 laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to specify in writing the duties and responsibilities of consultant and in each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing as required. Findings include: 1. SOP review revealed there was not a duties and responsibilities policy and procedure in the laboratory SOP. 2. An interview with Staff 31 (CMS 209) in a conference room on 7/23/2019 at approximately 12:30 p.m. confirmed there was not a duties and responsibilities policy and procedure in the laboratory SOP.

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 personnel document review and staff interview, the laboratory failed to

employ an individual who meets the requirements to perform the duties and responsibilities of a technical consultant (TC). Findings: For details 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 personnel document review and staff interview, the technical consultant /laboratory director (TC/LD) failed to meet the qualifications as TC as required. Findings include: 1. Personnel document review revealed the TC/LD was unqualified to fulfill the duties and responsibilities of TC due to lack of moderate-complexity laboratory experience. 2. An interview in the conference room on 7/23/19 with Staff #1 (CMS 209) at approximately 12:30 p.m. confirmed the aforementioned lack of laboratory experience.