

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1058713	(X3) Date Survey Completed 09/19/2018
Name of Provider or Supplier Upson Family Medical Center, Llc	Street Address, City, State 1512 Highway 19 North, Thomaston, 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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on September 19, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Casper 096 report and staff interview, the laboratory failed to enroll in Proficiency Testing (PT) for 2018. Findings include: 1. Review of the Casper 096 report revealed no reported scores for 2018. 2. Interview with staff #4 (CMS 209 form) on 9/19/18 at 10:15 AM in the breakroom, confirmed the lab did not participate in PT for the year of 2018.</p>
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</p>

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.

This STANDARD is not met as evidenced by:

Based on review of the Casper 096 report and staff interview, the laboratory failed to maintain a copy of the proficiency testing (PT) records. Findings include: 1. Review of the Casper 096 report revealed test scores for 2017, but no documents were retrievable at the time of the survey 2. Interview with staff #4 (CMS 209 form) on 9/19/18 at 10:15 AM in the breakroom, confirmed the lab did not have the PT records for the year of 2017.

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 review of the procedure manual (SOP) and staff interview, the laboratory failed to establish and follow written policies and procedures to assess laboratory personnel competency. Findings include: 1. SOP review revealed the laboratory failed to establish and follow a six-procedure policy and procedure for assessing laboratory personnel competency. 2. An interview with Staff #4 (CMS 209) in the breakroom on 9/19/18 at approximately 11::00 a.m. confirmed the SOP did not contain a six-procedure competency policy and procedure.

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 review of laboratory procedure manual (SOP) and staff interview, the laboratory failed to establish and follow written policies and procedures for Quality Assessment (QA) . Findings include: 1. Review of the SOP revealed the lack of QA policies and procedures . 2. Interview with staff #4 (CMS 209 form) on 9/19/18 at 11 AM in the breakroom, confirmed the lab did not have written QA policies and procedures.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on review of the procedure manual (SOP) and staff interview, the laboratory failed to establish and follow written policies and procedures for all tests, exams, and assays performed by the lab. Findings include: 1. SOP review revealed the laboratory failed to establish and follow written policies and procedures for analyzer or computer downtime, Quality Assurance, personnel training or competency, Proficiency testing, safety, eyewash maintenance, corrective actions, quality control on wet preps or potassium hydroxide (KOH), and the definition and reporting of alert/critical values. 2. An interview with Staff #4 (CMS 209) in the breakroom on 9/19/18 at approximately 11:00 a.m. confirmed the SOP did not contain all required aforementioned policy and procedures.

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 observation during the lab tour and staff interview, the lab failed to calibrate the Quest Horizon 642E centrifuge per the manufacturer. Findings include: 1. Observation during the lab tour revealed the Quest Horizon 642E centrifuge was last calibrated on March 28, 2015. 2. Interview with #4 staff (CMS 209 form) on 09/19/18 in the breakroom at approximately 1230 PM, confirmed the centrifuge had not been calibrated since 03/28/15.

D5439

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable

limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
Based on calibration document review and staff interviews, the lab failed to calibrate the Cell-Dyn Emerald analyzer every six (6) months as required by the manufacturer. Findings include: 1. Review of calibration data revealed the Emerald was last calibrated 02/02/18. Due August 2018, but no document of calibration performed to Date (9/19/18). 2. Interviews with testing personnel #2 and #4 (CMS 209 form) on 09/19/18 at approximately 1 PM in the breakroom, confirmed the last calibration was on 02/02/18 .

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on quality control (QC) document review and staff interview, the laboratory failed to perform and document QC on potassium hydroxide (KOH) slides. Findings include: 1. No QC documents were available to review on KOH slides at the time of survey. 2. An interview with Staff #4 (CMS 209) in the breakroom on 9/19/18 at approximately 11:20 a.m. confirmed controls were not performed on KOH preps.

D5523

PARASITOLOGY
CFR(s): 493.1264(a)(d)

The laboratory must have available a reference collection of slides or photographs and, if available, gross specimens for identification of parasites and use these references in the laboratory for appropriate comparison with diagnostic specimens. (d) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on review of quality control (QC) documents and staff interview, the laboratory failed to perform or document controls on saline wet mounts as required. Findings include: 1. Review of QC documents revealed no QC records available on wet mounts at the time of the survey for 2017 and 2018 thus far. 2. Interview with staff #4 (CMS 209 form) on 9/19/18 at approximately 11:20 a.m. in the breakroom, confirmed QC was not performed on wet mounts.

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 review of personnel records and staff interview, the laboratory director (LD) failed to meet the qualification requirements during the time period of April 1, 2018 to September 19, 2018. Findings include: Refer to D6003 for details

D6003

LABORATORY DIRECTOR QUALIFICATIONS

CFR(s): 493.1405 AND 493.1406

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director 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 had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or (b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407; or (b)(2)(ii)(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and (b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or (b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing; (b)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; (b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and (b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or (b)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and (b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing; (b)(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under 493.1406; or (b)(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located. Laboratory director qualifications on or before February 28, 1992 The laboratory director must be qualified to manage and direct the laboratory personnel and test performance. (a) The laboratory director must possess a current

license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (b)(1) Be a physician certified in anatomical 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; (b)(2) Be a physician who: (b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or (b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or (b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification; (b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (b)(4)(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or (b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either: (b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or (b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located. Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications.

This STANDARD is not met as evidenced by:

Based on review of personnel records and staff interview, the laboratory director (LD) failed to meet the qualification requirements during the time period of April 1, 2018 to September 19, 2018. Findings include: 1. Review of personnel records (4/1/18 to 9/19/18) revealed the LD did not have the proper lab training or experience required to direct a moderate complexity lab. 2. Interview with staff #4 (CMS 209 form) on 9/19/18 at approximately 10:30 AM in the breakroom, confirmed the lab director did not

meet the training or experience requirements.

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 each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of laboratory testing. Findings include: 1. SOP review revealed the LD failed to specify in writing the duties and responsibilities of each person engaged in the performance of all phases of laboratory testing. 2. An interview with Staff #4 (CMS 209) in the breakroom on 9/19/18 at approximately 1:00 p.m. confirmed the SOP did not contain a duties and responsibilities policy and procedure.