

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  25D0898810	<b>(X3) Date Survey Completed</b>  06/27/2023
<b>Name of Provider or Supplier</b>  Urgent Care Clinic Of Oxford	<b>Street Address, City, State</b>  1487 Belk Blvd, Oxford, MS	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The following condition level deficiencies were cited: D6000 - 42 C.F.R. 493.1403 Condition: Moderate Complexity Laboratory Director D6033 - 42 C.F.R. 493.1409 Condition: Technical Consultant -Moderate Complexity
<b>D6000</b>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on the review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, review of credentials for the individual designated as Laboratory Director (LD), and interview with testing personnel (TP) #1 at 2:30 p.m. on 6/27/2023, the laboratory does not have a laboratory director who meets the requirements of 493.1405 of this subpart. Findings Include: 1. Review of the CMS 209 personnel form and credentials provided for the laboratory director listed on the personnel form revealed this individual does not meet the qualification requirements of 493.1405 of this subpart. 2. TP #1 confirmed in an interview at 2:30 p.m. on 6/27/2023 that the laboratory director (LD) on the CMS 209 form was appointed in May 2022.</p>
<b>D6003</b>	<p><b>LABORATORY DIRECTOR QUALIFICATIONS</b> CFR(s): 493.1405 AND 493.1406</p> <p>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)</p>

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 the review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, credentials provided for the individual designated as laboratory director, and interview with testing personnel (TP) #1 at 2:30 p.m. on 6/27/2023, the laboratory does not have a laboratory director who meets the qualification requirements of 493.1405 of this subpart from May 2022 through 6/27/2023. Findings Include: 1. Review of the CMS 209 personnel form and credentials provided for the individual listed as laboratory director revealed this individual does not meet the qualification requirements of 493.1405 of this subpart. 2. TP #1 confirmed in an interview at 2:30 p.m. on 6/27/2023 that the laboratory director (LD) on the CMS 209 form was appointed in May 2022.

**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 the review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, credentials provided for the individual designated as technical consultant, and interview with testing personnel (TP) #1 at 2:30 p.m. on 6/27/2023, the laboratory does not have a technical consultant who meets the qualification

requirements of 493.1411 of this subpart. Findings Include: 1. Review of the CMS 209 personnel form and credentials provided for the technical consultant listed on the personnel form revealed this individual does not meet the qualification requirements of 493.1405 of this subpart. 2. TP #1 confirmed in an interview at 2:30 p.m. on 6/27 /2023 the individual listed as technical consultant on the CMS 209 form was appointed in May 2022.

**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 Centers for Medicare and Medicaid Services (CMS) 209 personnel form, documentation of personnel credentials available for review, and interview with the TP #1 at 2:30 p.m. on 6/27/2023, the laboratory did not have an individual designated as technical consultant who meets the qualification requirements of 493.1411 of this subpart from May 2022 through June 2023. Findings Include: 1. Review of the credentials for the individual listed as technical consultant on the CMS 209 personnel form revealed the individual did not qualify as technical

	<p>consultant based on the qualification requirements of 493.1411 of this subpart. 2. TP #1 confirmed in an interview at 2:30 p.m. on 6/27/2023 the individual listed as technical consultant on the CMS 209 form was appointed in May 2022.</p>
<p><b>D6049</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)(iii)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory testing records (including temperature logs, quality control results, proficiency testing results, and quality assessment results) from 11/16/2021 through 6/27/2023 and interview with the TP #1 at 2:30 p.m. on 6/27/2023, review of records had not been documented by a qualified technical consultant (TC) between April 2022 and June 2023 for 14 of 18 months. Findings Include: 1. The surveyor reviewed laboratory records from 11/16/2021 through 6/27/2023. The following records were not documented as reviewed by a qualified technical consultant for 14 of 18 months: a. Temperature logs (room, freezer, humidity and refrigerator) from 4/26/2022 through 6/27/2023 b. Medonic M Series quality control (QC) from 4/28/2022 through 6/27/2023 c. Proficiency Testing results for the 2nd and 3rd events of 2022 and 1st event of 2023 d. Monthly Quality Assessment checklist for 4/26/2022 - 6/20/2023 2. Interview with TP #1 at 2:30 pm on 6/27/2023 confirmed there was no documented review of these records by a qualified TC.</p>
<p><b>D6053</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of testing personnel records since 11/16/2021, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, and interview with testing personnel (TP) #1 at 2:30 p.m. on 6/27/2023, a qualified technical consultant (TC) failed to evaluate and document the performance of 1 of 1 new TP (TP #3) at least semiannually during the first year of moderate complexity testing. Findings include: 1. Testing personnel performing moderate complexity testing are required to have a competency evaluation by a qualified technical consultant at least semi-annually during the first year of testing. 2. TP #3 had an initial training date of 9/13/2022 and a 6-month competency evaluation on 3/1/2023 performed by an individual who did not qualify as TC (1 of 1 6-month competency evaluations due). 3. TP#1 confirmed in an interview at 2:30 p.m. on 6/27/2023 that the 6-month competency evaluation on TP #3 was performed by an individual who did not qualify as TC.</p>
<p><b>D6054</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the</p>

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 surveyor review of laboratory testing personnel (TP) records including the Centers of Medicare and Medicaid Services (CMS) 209 personnel form and interview with TP #1 at 2:30 p.m. on 6/27/2023, a qualified technical consultant failed to evaluate annually and document the performance of testing personnel TP #1 and TP #2 (2 of 2 TP due for annual competency evaluations) who are responsible for performing moderate laboratory testing. Findings include: 1. Testing personnel performing moderate complexity testing are required to have a competency evaluation by a qualified technical consultant at least annually after the first year of testing. 2. The surveyor reviewed competency evaluations and the CMS-209 personnel form. 3. The annual competency evaluations available for review on TP #1 and TP #2 were not performed by a qualified Technical Consultant (2 of 2 annual evaluations due in 2022). 4. TP#1 confirmed in an interview at 2:30 p.m. on 6/27/2023 that the annual competency evaluations on TP #1 and TP #2 for 2022 were performed by an individual who did not qualify as TC.