

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0668015	(X3) Date Survey Completed 03/22/2021
Name of Provider or Supplier Discovery Pediatrics	Street Address, City, State 10313 Georgia Av Suite 303, Silver Spring, 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
D0000	The laboratory is in compliance with the regulatory requirements of 42 CFR 493 for Medicare/Medicaid-approved and CLIA-certified laboratories.
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR 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 review of credentials received on 05/04/2021, phone interview with the acting laboratory director (LD) on 03/22/2021, the laboratory failed to provide documentation to show that the acting LD meets the minimum qualifications to become the permanent LD (D6003); the LD listed on the CLIA certificate failed to document review of the proficiency testing results (D6018); and LD listed on the CLIA certificate failed to document review of the quality assurance reviews (D6022).</p>
D6003	<p>LABORATORY DIRECTOR QUALIFICATIONS 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) 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</p>

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 a phone interview with the acting laboratory director (LD) on 03/22/2021, the acting LD failed to provide documentation showing that the LD met the requirements to qualify as the LD under the CLIA regulations. Findings: 1. According to the CLIA application on file in the federal database, Lawrence Cohen, MD is listed as the director of the laboratory. 2. The acting LD stated the LD listed on the CLIA certificate was no longer with the practice. The surveyor stated that the acting LD would need to submit documentation showing that the minimum CLIA requirements were met to become the LD, e.g., a copy of the Director's medical license, medical diploma and board certification must be submitted, and documentation showing training and experience listed in (b)(2)(ii), (b)(2)(ii)(A), (b)(2)(ii)(B) or (b)(2)(ii)(C). (See the regulations listed above). 3. The "Laboratory Licensing Change Form 2020" and documentation that was received at the Office of Health Care Quality on 05/04/2021 did not include the required documentation to qualify the acting LD as a laboratory director of a moderately complex CLIA laboratory. 4. As of 05/17/2021, the acting LD failed to provide documentation to verify minimum requirements to be the LD of the laboratory.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(4)(iii)

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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:
Based on a phone interview with the acting laboratory director (LD) on 03/22/2021, the LD listed on the CLIA certificate failed to document review of the proficiency testing (PT) results and ensure corrective actions were taken and documented.
Findings: 1. The Laboratory Personnel Report (CLIA) was submitted on 03/01/2021 along with the credentials of the staff listed on the report. The form did not indicate who was the qualified clinical consultant and technical consultant. The form was signed by the acting LD but the credentials that were submitted showed that the LD was not qualified. Cross refer to D6003 for details. 2. The PT records for chemistry and non-chemistry for 2019 and 2020 were reviewed. 3. The PT records for 2020 for chemistry and non-chemistry showed that someone other than the LD listed on the CLIA certificate reviewed the results. 4. During the phone interview on 03/22/2021 at 1:00 PM, the acting LD confirmed that he was currently performing the PT reviews.

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 a phone interview with the acting laboratory director (LD) on 03/22/2021, the LD listed on the CLIA certificate failed to document review of the monthly quality assurance (QA) reviews. Findings: 1. The Laboratory Personnel Report (CLIA) was submitted on 03/01/2021 along with the credentials of the staff listed on the report. The form did not indicate who was the qualified clinical consultant and technical consultant. The form was signed by the acting LD but the credentials that were submitted showed that the LD was not qualified. Cross refer to D6003 for details. 2. The QA reviews from January 2019 through January 2021 were reviewed. 3. The QA reviews showed that as of November 2019 the acting LD was documenting review of the findings. 4. During the phone interview on 03/22/2021 at 1:00 PM, the acting LD confirmed that he was currently performing the QA reviews.