Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	30D0084807	02/01/2019
Name of Provider or Supplier	**Street Address, City, State**	
Derry Pediatrics	43 B Birch St, Derry, NH	

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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to follow manufacturer's instructions and perform control testing for bacteriology testing in 2017, 2018 and 2019. Refer to tags D5411 and D5471.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to follow the bacitracin (Taxo A) disk manufacturer instructions for the selection of appropriate media used for moderately complex bacteriology testing from March 2017 to January 2019. Findings include: 1) Review on 2/1/2019 of the package insert "BD BBL Taxo Discs for Differentiation of Group A Streptococci" (Strep) revealed the "Taxo A discs

	are not for use directly with clinical specimens or other sources containing mixed flora." The Taxo A disks may only be used on primary cultures when throat specimens are inoculated onto Selective Strep Agar (SSA). 2) Review on 2/1/2019 of control records titled "Quality Control Strep Agar Media" from 3/27/2017 to 1/21 /2019 revealed the laboratory received 19 new shipments; 16 of 19 shipments were Triptic Soy Agar with 5% sheep blood (TSA), 1 shipment was Phenyl Ethyl Alcohol with 5% sheep blood (PEA) agar, and 2 shipments were SSA. Dates, lot numbers, and media types received are as follows: Date Lot Number Media 03/27/2017 1703002 TSA 04/06/2017 1702301 TSA 05/09/2017 1705801 TSA 06/02/2017 1708612 SSA 06/26/2017 1710001 TSA 07/17/2017 1712109 TSA 10/09/2017 1723309 PEA 11/07 /2017 1724100 TSA 12/07/2017 1729000 TSA 12/20/2017 1729700 TSA 02/02/2018 7333521 TSA 02/09/2018 1800803 TSA 02/20/2018 1801000 TSA 06/12/2018 1807100 TSA 07/25/2018 1813400 TSA 08/22/2018 1814900 TSA 09/13/2018 1818300 TSA 10/08/2018 1822103 TSA 01/21/2019 1833707 SSA 3) Review on 2/1 /2019 of package inserts for TSA revealed the media is non-selective and supports the growth of mixed flora including Streptrococcus and Staphylococcus species, and Escherichia coli. 4) Review on 2/1/2019 of the package insert for PEA revealed it is supportive of gram positive organisms including Streptococcus and Staphylococcus species. 5) Interview on 2/1/19 at 9:45 a.m. with TP1 (testing personnel) revealed throat swab specimens were inoculated onto PEA and TSA media and Taxo A disks were applied directly to the primary cultures. 6) The laboratory performs 376 throat cultures annually using the Taxo A disks for the presumptive identification of beta-hemolytic group A Strep. 7) Moderately complex testing for the presumptive identification of beta-hemolytic group A Strep must include throat swab specimens used directly with selective media, hemolysis, and bacitracin disk.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to check 12 of 12 lot number/shipments of bacitracin (Taxo A) disks for negative reactivity from April 2017 through January 2019. Findings include: 1) Review on 2/1/2019 of Taxo A disk control records titled "Strep A Disc Quality Control" from 4/20/2017 to 1/30/2019 revealed 12 of 12 shipments of Taxo A disks were received and no control results were documented for negative reactivity. Date and lot numbers of Taxo A disks received are as follows: Date Lot Number 04/20/2017 6321853 09/12/2017 122676 09 /12/2017 120469 10/03/2017 122676 10/03/2017 120469 11/07/2017 7052949 12/07 /2017 6187854 02/02/2018 7331791 06/13/2018 7321994 09/13/2018 8050848 10/10 /2018 8050848 01/30/2019 8085653 2) Interview on 2/1/2019 at 9:45 a.m. with TP2 (testing personnel) revealed the laboratory did not check the 12 Taxo A disk shipments for negative reactivity. 3) The laboratory performs 376 throat cultures annually using the Taxo A disks for the presumptive identification of beta-hemolytic group A Streptococcus.

D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to meet qualification requirements and provide overall management and direction for bacteriology testing in 2017, 2018, and 2019. Findings include: 1) The laboratory director failed to have at least one year experience directing a laboratory performing high complexity testing. Refer to tag D6078. 2) The laboratory director failed to ensure test methodologies used for the presumptive identification of beta-hemolytic group A Streptococcus had the capability of providing quality results required for patient care. Refer to tag D6085. 3) The laboratory director failed to ensure that the quality control program for bacitracin disks, used for the presumptive identification of beta-hemolytic group A Strep, were established and maintained to assure the quality of laboratory results. Refer to tag D6093 (A). 4) The laboratory director failed to ensure that quality control was maintained to identify the failure in the laboratory's use of inappropriate media required for the quality of procedures in the presumptive identification of beta-hemolytic group A Streptococcus. Refer to tag D6093 (B).
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (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) Be a doctor of medicine, a 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)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; 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 and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be

	qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to meet qualification requirements for experience directing a laboratory performing high complexity bacteriology testing in 2017, 2018, and 2019. Findings include: 1) Review on 2/1/2019 on 2/1/2019 of culture media records revealed the laboratory did not follow manufacturer's instructions and did not use the appropriate bacteriology media for the presumptive identification of beta-hemolytic group A Streptococcus (Strep) testing. Off label use and use of non-selective media for this testing constitutes high complexity testing. 2) Review on 2/1/2019 of the laboratory director's qualifications revealed the LD failed to have one year or more of experience directing a high complexity laboratory.
D6085	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3) The laboratory director must ensure that the test methodologies selected have the capability of providing the quality of results required for patient care. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to ensure test methodologies used for the presumptive identification of beta-hemolytic group A Streptococcus (Strep) had the capability of providing quality results required for patient care in 2017, 2018, and 2019. Findings include: 1) Review on 2/1/2019 of the package insert "BD BBL Taxo Discs for Differentiation of Group A Streptococci" revealed the "Taxo A discs are not for use directly with clinical specimens or other sources containing mixed flora." The Taxo A disks may only be used when throat specimens are inoculated using Selective Strep Agar (SSA). 2) Review on 2/1/2019 of control records titled "Quality Control Strep Agar Media" from 3/27/2017 to 1/21 /2019 revealed the laboratory received 16 shipments of Tryptic Soy Agar with 5% sheep blood (TSA) and 1 shipment of Phenyl Ethyl Alcohol (PEA) with 5% sheep blood agar; 17 of 19 shipments of media received failed to be SSA media to prevent the growth of mixed flora. Further review revealed no documentation that the control logs had been reviewed for acceptable results. 3) Review on 2/1/2019 of package inserts for TSA revealed it is non-selective and supports the growth of mixed flora including Strep species, Staphylococcus (Staph) species, and Escherichia coli. 4) Review on 2/1/2019 of the package insert for PEA revealed it is supportive of gram positive organisms including Strep and Staph species. 5) Interview on 2/1/19 at 9:45 a. m. with TP1 (testing personnel) revealed throat swab specimens were inoculated onto PEA and TSA media and Taxo A disks were applied directly to the primary cultures. 6) The laboratory performs 376 throat cultures annually using the Taxo A disks for the presumptive identification of beta-hemolytic group A Strep. 7) Off label use and use of non-selective media for this testing constitutes high complexity testing. Moderately complex testing for the presumptive identification of beta-hemolytic group A Strep must include throat swab specimens used directly with selective media, hemolysis, and bacitracin disk.

D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: A. Based on record review and staff interview, the laboratory director failed to ensure that the quality control program for bacitracin (Taxo A) disks used for the presumptive identification of beta-hemolytic group A Strep was established and maintained to assure the quality of laboratory results in 2017, 2018, and 2019. Findings include: 1) Review on 2/1/2019 of Taxo A disk control records from 4/20 /2017 to 1/30/2019 revealed 12 of 12 new shipments of Taxo A disks were received and not checked for negative reactivity. 2) Interview on 2/1/2019 at 9:45 a.m. with TP2 (testing personnel) confirmed the laboratory did not check the 12 Taxo A disk shipments for negative reactivity. B. Based on record review and staff interview, the laboratory director failed to ensure that the quality control program was maintained to identify the laboratory's failure to select and use required media for the presumptive identification of beta-hemolytic group A Streptococcus (Strep) in 2017, 2018, and 2019. Findings include: 1) Review on 2/1/2019 of the laboratory's quality control procedure titled "Quality control for Media for Strep Select Agar" revealed instruction for the use of Selective Strep Agar (SSA). Further review revealed the use and expected result of control organism Escherichia coli (E. coli) was "no growth." 2) Review on 2/1/2019 of the control log titled "Quality Control Strep Agar Media" from 3/27/2017 to 1/21/2019 revealed 16 of 19 new shipments of media were Triptic Soy Agar with 5% sheep blood (TSA). E. coli control testing was performed on 16 of 16 TSA plates, with the expected result documented on the log as "no growth" and resulted as "neg" for negative. Further review revealed no documentation that the control logs had been reviewed for acceptable results. 3) Review on 2/1/2019 of the package insert for the TSA plates revealed the E. coli is expected to grow on TSA plates. 4) Review on 2/1/2019 of the package insert "BD BBL Taxo Discs for Differentiation of Group A Streptococci" revealed the "Taxo A discs are not for use directly with clinical specimens or other sources containing mixed flora" (includes E. Coli). 5) Interview on 2/1/2019 at 9:45 a.m. with TP2 (testing personnel) revealed TP2 believed the purpose of performing E. coli control testing was to demonstrate the result was negative for presumptive identification of beta-hemolytic group A Strep and results for E. coli were documented as "neg."
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on record review and staff interview, the testing personnel failed to meet qualification requirements for performing highly complex bacteriology testing in 2018 and 2019. Refer to tag D6171.

D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) 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 or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet

	the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on record review and staff interview, testing personnel failed to meet qualification requirements for performing highly complex bacteriology testing in 2018 and 2019. Findings include: 1) Review on 2/1/2019 of testing personnel records revealed 3 of 3 records reviewed failed to have documentation qualification requirements for performing presumptive identification of beta-hemolytic group A Streptococcus (Strep). TP3 and TP4 (testing personnel) were hired in November 2018 and TP5 (testing personnel) was hired in December 2018. 2) Interview on 2/1/2019 at 9:15 a.m. with TP1 (testing personnel) confirmed documentation of educational qualifications were not included in the personnel records for TP3, TP4, and TP5.