Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	09D0208515	09/30/2019
Name of Provider or Supplier	**Street Address, City, State**	
Foxhall Pediatrics, Pc	3301 New Mexico Ave, Nw, Washington, DC	

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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation, the laboratory (lab) did not ensure that the refrigerator located in the testing area and used to store lab reagents, was free from food items to ensure protection from biohazard materials. Findings: 1. It was observed on the day of survey that the side by side refrigerator/freezer located in the lab testing area had signage on the door showing the image of a hand reaching for a drinking cup and a red circle with a line through the circle, imaged overtop of the hand and cup, symbolizing that the refrigerator be free of food or drink; and 2. Inside the freezer on the bottom shelf was a bag of frozen squeeze pops.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on record review, the laboratory written procedures did not include instructions for performing the Kirby-Bauer quality control check for the antimicrobial disk and organism combination of augmentin and E. coli in duplicate. Findings: 1. The quality control worksheet to document the results of the disk diffusion (Kirby-Bauer) control checks lists the drug and organism combination of augmentin (AMC 20/10) and E. coli in duplicate and results for this drug and organism combination are documented in duplicate on the quality control worksheets. 2. On the Kirby-Bauer quality control worksheet dated October 20, 2019, August 10, 2019 and April 30, 2019, The antimicrobial disk augmentin (lot number 8177887) is tested in duplicate with E. coli (strain 25922); and 3. The laboratory written procedure did not include written procedures to test the Augmentin (AMC 20/10) disk with E.coli in duplicate, and there were no written instructions for corrective actions if one of the AMC 20/10 and E. coli disk combination checks failed to meet the laboratory's criteria for acceptability and the duplicate check did meet the laboratory's criteria for acceptability.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on record review and observation, the laboratory did not ensure that reagents for bacteriology testing were not used past expiration. Findings: 1. The "Kirby Bauer Quality Control" worksheet reviewed on the day of survey that was in the lab was incomplete, this record is the laboratory's documentation for performing daily antimicrobial susceptibility quality control checks; 2. The laboratory did not enter the lot numbers and expiration dates of the antimicrobial disks (ampicillin, augmentin, cephalothin, nitrofurantoin, trimethoprim/sulfamethoxazole and duplicate augmentin) on the "Kirby Bauer Quality Control" worksheet dated August 10, 2019, this record was observed in the laboratory on the day of survey, it was signed on August 10, 2019 by the technician and by the director. The surveyor requested additional records from the laboratory in an e-mail dated October 6, 2019, these records were provided in an e-mail from the lab on November 2, 2019. The missing information (lot numbers and expiration dates) was filled in on the records provided in the e-mail from the laboratory. The completed form sent in the e-mail was the same document observed in the lab (the hand written signatures, dates and test results were an exact match), but the document in the e-mail now included the missing data. The missing data was not initialed and dated to show who amended the record and when it was amended; 3. The laboratory performed quality control testing on the Remel staph latex test kit on July

5, 2019 and August 21, 2019. There were two test kits documented on the quality control record. Test kit lot 293539 expired on June 4, 2019, the more recent test kit lot 511285 expired on August 6, 2020, but this test kit was not received and opened until August 22, 2019. The record shows that quality control testing was performed on expired test kits on July 5, 2019 and August 21, 2019 and there was no written corrective action record to ensure patient testing was not performed on these two days using expired test kits; 4. The laboratory performed quality control testing on expired mueller-hinton agar plates, and there was no written corrective action report to determine if patient testing was also performed on expired media; a) On August 13, 2019 quality control testing was performed using mueller hinton agar (lot 438597) that expired August 11, 2019, for the Kirby-Bauer drug (antimicrobial disk) microbe combination, oxacillin and S.aureus. b) On May 6, 14 and 21, 2019 quality control testing was performed using mueller hinton agar (lot 1902206) that expired on April 30, 2019 for the kirby-bauer drug microbe combination, oxacillin and S. aureus. c) On February 12, 2019 quality control testing was performed using mueller hinton agar (lot 1830306) that expired February 5, 2019, for the kirby-bauer drug microbe combination, oxacillin and S.aureus. d) On December 11, 2018 quality control testing was performed using mueller hinton agar (lot 1824009) that expired December 4, 2018, for the kirby-bauer drug microbe combination, oxacillin and S.aureus. e) On October 18 and 23, 2018 quality control testing was performed using mueller hinton agar (lot 1818413) that expired October 9, 2018, for the kirby-bauer drug microbe combination, oxacillin and S.aureus. 5. The laboratory performed quality control testing on expired catalase reagent. Lot number 7088559 that expired August 15, 2018, the more current lot 7099525 with an expiration date of July 15, 2020 was not opened until February 12, 2019, but quality control testing was performed on August 27, 2018, September 18, 2018, October 15, 2018, November 7, 2018, December 11, 2018 and January 15, 2019; 6. The laboratory performed quality control testing on expired indole reagent. Lot number 7347501 expired on April 30, 2019 was used on May 21, 2019, June 1, 2019, July 10, 2019, August 6 and 27, 2019 and September 18, 2019; 7. The laboratory did not have written corrective action plans to ensure that expired reagents were not used for patient testing, determine if any patient test results were affected and provide corrective actions for patients that were identified at risk. 8. Two lot numbers of test kits are reported on the staph latex quality control worksheet that begins on December 19, 2016 and ends with testing performed on January 15, 2019. Lot number 814753 expired on January 31, 2018 and lot number 293539 opened on November 5, 2018 (expires June 4, 2019). Each test kit includes positive and negative controls for that lot, but the worksheet shows that the kit controls that expired on January 31, 2018 (kit lot number 814753 were also used to check the positive and negative reactivity for kit lot number 293539 (this kit was opened on November 15, 2018; 9. Two lot numbers of test kits are reported on the staph latex quality control worksheet that begins February 18, 2019 and ends with testing performed on October 21, 2019. Lot number 293539 expired on June 4, 2019 and lot number 511285 opened on August 22, 2019 (expires August 6, 2020). Each test kit includes positive and negative controls for that lot, but the worksheet shows that the kit controls that expired on June 4, 2019 (kit lot number 293539 were also used to check the positive and negative reactivity for kit lot number 511285 that was opened on august 22, 2019; and 10. The "pathodx" monthly quality control worksheet for strep antigen grouping (test records beginning on January 10, 2018 and ending on September 5, 2019) shows that reagent 1 expired June 2019 and reagent 2 and 3, both expired on May 2019, but the expired reagents (reagent 2 and 3) were used for quality control testing on June 5, 2019 and expired reagents 1, 2 and 3 were used for quality control testing on July 8, 2019, August 23, 2019 and September 5, 2019 for quality control testing. No documented corrective action was observed, to determine if patient

	testing was also performed using expired test kits.
D5419	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(e) Components of reagent kits of different lot numbers must not be interchanged unless otherwise specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of quality control records, the laboratory used quality control reagents from one test kit to another each kit was a different lot number. Findings: 1. Two lot numbers of test kits are reported on the staph latex quality control worksheet that begins on December 19, 2016 and ends with testing performed on January 15, 2019. Lot number 814753 expired on January 31, 2018 and lot number 293539 opened on November 5, 2018 (expires June 4, 2019). Each test kit lot includes positive and negative controls, but the worksheet shows that the kit controls that expired on January 31, 2018 (kit lot number 814753 were also used to check the positive and negative reactivity for kit lot number 293539 (this kit was opened on November 15, 2018; and 2. Two lot numbers of test kits are reported on the staph latex quality control worksheet that begins February 18, 2019 and ends with testing performed on October 21, 2019. Lot number 293539 expired on June 4, 2019 and lot number 511285 opened on August 22, 2019 (expires August 6, 2020). Each test kit includes positive and negative controls, but the worksheet shows that the kit controls that expired on June 4, 2019 (kit lot number 293539) were also used to check the positive and negative reactivity for kit lot number 511285 that was opened on august 22, 2019;
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on record review and observation, the laboratory did not perform thermometer preventive maintenance as indicated on the "Thermometer Calibration and Validation" worksheet. Findings: 1. The laboratory maintenance worksheet for thermometer calibrations shows that the last calibration performed for thermometer #4 was dated May 10, 2016, even though the worksheet shows that the next calibration is due May 10, 2017; and 2. It was observed on the day of survey that the laboratory did not have current thermometer calibration records.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and observation, the laboratory (lab) did not have procedures in place for reliable documentation of quality control checks (documentation of the receipt and physical characteristics of the media) performed on bacteriology media received from manufacturer. Findings: 1. The lab was documenting the receipt of the microbiology test media (media quality control) on the manufacturers quality control certificates, as each certificate was dated; 2. The biplate media (lot 124246) and blood agar media certificate of analysis were both dated September 12, 2019 along with the notation "ok", there was no written procedure stating what the date was in reference to and what the notation "ok" referred to; 3. It was observed that the dermatophyte test media in the refrigerator (lot numbers 444455 with an expiration date of February 4, 2020 and 1907914 with an expiration date of March 19, 2020 was not documented in the media quality control records, the last record for this media was made on September 24, 2018 (lot number 1819314) and this batch expired on 2019-07-12. The use of the dermatophyte test media was discontinued on June 7, 2019 as stated on the proficiency test corrective action form for the first event of 2019; and 4. In 2018 and 2019, the lab was checking prepared media upon receipt for physical characteristics as the quality control procedure, but did not have an approved individualized quality control plan at that time, the plan was not approved by the lab director until September 11, 2019.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on record review of dermatophyte patient test log from September 17, 2018 through September 12, 2019, four of twenty-two dermatophyte test records did not identify the testing person as they were not initialed to show the identity of the testing person.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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: Based on record review, the laboratory director did not perform quality assurance reviews as described on the microbiology quality control worksheet. Findings: 1. The quality control record for antimicrobial susceptibility testing (Kirby-Bauer) dated April 30, 2019 was not reviewed by the laboratory director. There is a place on the quality control record for the director's review, and there was no signature or date recorded on the document for this quality assurance review.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on record review, the laboratory (lab) director did not have procedures in place to ensure that the competency evaluations performed on Technical Supervisor #1 acting as testing person were conducted by the lab director or other qualified individual. Findings: 1. Technical Supervisor #1 was identified as technical consultant on the "form CMS-209", there was no one designated as technical supervisor on this form even though high complexity bacteriology testing is performed (Kirby-Bauer antimicrobial susceptibility and throat culture procedures to identify Group A strep using sheep blood agar plates). Personnel records show that technical supervisor #1 acted as technical supervisor, and on a "Personnel Evaluation" dated March 9, 2018 Technical Supervisor #1 was evaluated as "laboratory technologist, supervisor + consultant" by the lab director. Technical Supervisor #1 and Testing Person #2 both performed testing person duties in bacteriology. Testing Person #2 was not named as a technical supervisor on the "form CMS-209", but is named as testing person; 2. On April 3, 2018 and May 2, 2019 Testing Person #2 performed competency evaluations on Technical Supervisor #1 by observation of pre analytical and post urine culture testing as documented on the competency assessment record, even though testing person # 2 was not evaluated and approved as technical supervisor by the lab director; 3. On April 30, 2019 Technical supervisor #1 had a competency assessment performed by observation, as documented on the "Direct Observation and Competency Assessment Tool for the Coulter", the reason for observation was not reported on the form, as requested on the form. Technical Supervisor #1 signed this form as both "Validator" and "Employee", showing that he performed his own competency review; and 4. The competency assessment records were observed by the surveyor on the day of survey.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.

	This CONDITION is not met as evidenced by: Based on record review, the technical supervisor did not provide technical supervision in accordance with 493.1451. The laboratory was performing high complexity bacteriology testing and Technical Supervisor #1 was performing technical supervisor duties, and was identified as such in personnel records, but Technical Supervisor # 1 reported to the surveyor in an e-mail dated October 21, 2019 that he was no longer performing technical consultant (supervisor) duties as of July 2019, the laboratory's written responsibility and duties statement did not reflect this change, In addition testing person #2 who was not assigned technical supervisor duties according to written procedures, did perform these duties when he performed competency checks on Technical Supervisor #1 on April 3, 2018; The technical supervisor failed to perform quality assurance reviews, to ensure that the laboratory (lab) was enrolled in a proficiency testing program commensurate with the services offered (D6116); failed to ensure that bacteriology quality control results are documented in an accurate and reliable manner (D6117); failed to evaluate competency of testing personnel (D6120); and failed to identify problems through review of quality control records, that indicated problems requiring remedial training of staff (D6123).
D6116	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(3) The technical supervisor is responsible for enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered. This STANDARD is not met as evidenced by: Based on record review, the technical supervisor for microbiology testing did not perform quality assurance reviews, to ensure that the laboratory (lab) was enrolled in a proficiency testing program commensurate with the services offered. Findings: 1. The laboratory enrolls in a proficiency testing program with a proficiency testing provider. The provider sends the laboratory unknown samples to test throughout the year of enrollment. The laboratory tests the unknown samples and reports results to the provider for evaluation, the provider evaluates the results and scores the lab's performance; 2. Review of 2018 and 2019 proficiency testing records for bacteriology shows that the lab was not consistently challenged for antimicrobial susceptibility testing, as the lab would only perform and report this testing for organisms it identifies as E. coli from urine samples. In an e-mail dated November 2, 2019 from the lab, the lab stated that it did not have any antimicrobial susceptibility challenges in both 2018 and 2019 because the proficiency test provider did not provide E. coli as a test organism challenge, and the lab will only perform susceptibility testing on organisms identified as E. coli; 3. Review of proficiency testing records did not show that the laboratory (having written procedures for testing and reporting different groups of streptococcus), performed these tests for proficiency testing in 2018 and 2019; and 4. There was no quality assurance review of proficiency testing challenges and record of this review by the technical supervisor to ensure that the proficiency testing programs that the lab is enrolled in is sufficient for the testing performed.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program

	appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on record review, the technical supervisor did not ensure that bacteriology quality control results are documented in an accurate and reliable manner. Findings: 1. The Patho dx monthly quality control worksheet is for strep antigen grouping and is used to document the results for antisera checks for groups A, B, C, F and G; 2. The manufacturer states to check the specificity of the agglutination or negative control, and for each grouping latex to be assessed dispense one drop of extract prepared and one drop of latex reagent; and 3. Type A and Type B antisera reagents were recorded on the quality control worksheet that begins on January 10, 2018, but the quality control test results only had one positive and one negative result reported for each day of testing. There was no documentation to show which antisera the results were intended for or if both group A and group B antisera was checked for positive and negative reactivity for each of those days.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on observation of the personnel record for Testing Person #2, the technical supervisor did not perform a competency review in 2018 for this employee as observed on the day of survey.
D6123	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iii) 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. This STANDARD is not met as evidenced by: Based on record review, the technical supervisor did not perform adequate reviews of quality control records to ensure that the records were completed in an accurate and reliable manner and identifying problems requiring additional training of staff. 1. The technical supervisor review of bacteriology quality control worksheets failed to identify problems in the work records that would require remedial training of testing persons; 2. The technical supervisor failed to identify that testing persons were using expired reagents to perform bacteriology quality control tests. See D5417 for findings; and 3. The technical supervisor failed to identify that testing personnel were

	interchanging quality control reagents between different lots of test kits. See D5419 for findings.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on record review, the laboratory testing person did not complete quality control worksheets as described on the microbiology quality control worksheet. Findings: 1. The quality control record for antimicrobial susceptibility testing (Kirby-Bauer) dated April 30, 2019 was not complete as the testing person did not identify himself on the worksheet by initialing the record as indicated on the worksheet. There is a place on the quality control record for the testing persons initials; and 2. On the quality control record for antimicrobial susceptibility testing dated January 10, 2018, the testing person assigned the same lot number (6270811) for two different antimicrobial disks ampicillin and the duplicate augmentin antimicrobial disks reported on the document.