Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0686947	09/25/2019
Name of Provider or Supplier	**Street Address, City, State**	
Piedmont Pediatrics	105 Collier Road Suite 4060, Atlanta, 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	On October 11, 2019, an off site followup review was completed. The report revealed that corrective action was found to be completed or acceptable progress made on the deficiencies cited. All deficiencies have been corrected. The facility is in compliance with with all regulations surveyed.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on observation during the lab (pods) tour, review of the manufacturer package insert, and staff interview, the laboratory failed to follow manufacturers' instructions for performing the urine macroscopic test. Findings: 1. Observation of lab pod #1 revealed an expired opened bottle of Siemens Multistix 10SG lot #711016 with the expiration date of 05/31/19 on the counter. Further observation of lab storage cabinets revealed: 1 unopened bottle of the aforementioned reagent strips; 1 bottle of urine dip strips lot # 706032 with an expiration date of 11/30/18, and 1 bottle of urine dip strips lot # urs6050108 with an expiration date of 06/30/18. 2. Review of the manufacturer package insert revealed: "Check the expiration date on the reagent strip bottle; if the date has passed, discard and get a new bottle" and "use of reagent strips beyond the expiration date may yield inaccurate results". 3. Interview with the clinical manager/ general supervisor (CMS 209 form) on 9/25/19 at approximately 10:30 AM in lab pod #1, confirmed the urine reagent strips were expired.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)

	(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control records for bacteriology and staff interview, the facility failed to perform the required sterility check on each batch of media used to perform throat cultures. Findings include: 1. Review of quality control (QC) records reveals the laboratory is not performing sterility check on Strep culture media. 2. Interview with the clinical manager/general supervisor on 9/25/19 at 11:57 am reveals the laboratory is not aware of the new requirement to perform sterility check and confirms they are not performing the sterility check as required.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the laboratory records, procedure manual (SOP), and staff interviews, the laboratory director failed to ensure the personnel receive the appropriate training for the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. Findings include: 1. Review of the SOP revealed the lack of a written policy to train and evaluate employees prior to performing patient testing. 2. Review of the laboratory's records revealed no documentation of training for 6 of 6 testing personnel listed on the CMS 209 form. 3. Interview with the clinic manager/general supervisor 09/25/19 at approximately 11:50 AM in room #9, confirmed the lab did not have the aforementioned policy or documentation.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory records and staff interviews, the technical supervisor (laboratory director) failed to evaluate and document the competency of testing personnel at least semiannually during the first year of testing patient specimens. Findings include: 1. Review of the laboratory's records revealed no

	documentation of semiannual competency for 6 of 6 testing personnel listed on the CMS 209 form. 2. Interview with the clinic manager/general supervisor (CMS 209) on 9/25/19 at approximately 11:50 AM in room #9, confirmed the lab did not have the aforementioned documentation.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of the laboratory records and staff interviews, the technical consultant (laboratory director) failed to evaluate and document the competency of testing personnel at least annually after the first year. Findings include: 1. Review of the laboratory's records revealed no documentation of annual competency for 6 of 6 testing personnel listed on the CMS 209 form. 2. Interview with the clinic manager /general supervisor on 9/25/19 at aprroximately 11:50 AM in room #9, confirmed the lab did not have the aforementioned documentation.