Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D1027317	(X3) Date Survey Completed 11/14/2018
Name of Provider or Supplier Haymarket Pediatrics, Plc	**Street Address, City, State** 4424 Costello Way, Haymarket, VA	
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	An announced CLIA recertification survey was conducted at Haymarket Pediatrics, PLC on November 14, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
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 a review of the laboratory's patient test logs, Uri-Check Inspection Logs and interviews, the laboratory failed to monitor and evaluate analytic quality by failure to document the ability to support and inhibit growth, and produce a specific biochemical response for nine (9) of nine (9) lot numbers of Troy Biologicals URICHEK media received from January 1, 2017 to November 14, 2018 (Cross Reference D5477).
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 patient test logs, Uri-Check Inspection Logs and interviews, the laboratory failed to document the ability to support and inhibit growth, and produce a specific biochemical response for nine (9) of nine (9) lot numbers of Troy Biologicals URICHEK media received from January 1, 2017 to November 14, 2018. Findings include: 1. Review of the patient test logs and Uri-Check Inspection Logs revealed that the laboratory received and utilized nine (9) lot numbers of Troy Biologicals URICHEK media from January 1, 2017 to November 14, 2018. The following are the lot numbers were received and number of patients tested: Lot 7D19A-utilized for ten (10) patient cultures; Lot 7A16A-utilized for forty-five (45) patient cultures; Lot 6L01A-utilized for seventeen (17) patient cultures; Lot 6H10A-utilized for thirty-eight (38) patient cultures; Lot 7E03A-utilized for twelve (12) patient cultures; Lot 7H24A-utilized for twenty-five (25) patient cultures; Lot 8A31A-utilized for fifty-two (52) patient cultures; Lot 8D20A-utilized for nineteen (19) patient cultures; Lot 8H01A-utilized for eight (8) patient cultures. A total of 9 lot numbers and 226 patient cultures. 2. Review of the Uri-Check Inspection Logs revealed no documentation of the ability of each lot number of media to support or inhibit specific organism growth, and produce a specific biochemical response. 3. The surveyor requested to review the quality control documentation for the media. The documentation was unavailable for review. The laboratory nurse manager stated that they save the "Certificate of Analysis" for each lot number of media received. 4. In an interview at approximately 12:15 PM, the laboratory nurse manager confirmed that the laboratory failed to document the ability to support and inhibit growth, and produce a specific biochemical response for each lot or batch of media received. **This is a repeat deficiency.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(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 the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, quality assurance (QA) policy, and interview, the technical consultant failed to perform and document annual competency assessments for two (2) of two (2) TP in 2017. Findings include: 1. Review of the CMS-209 form revealed that the lab director also performs the duties of technical consultant and that there were 2 TP performing patient testing in 2017. (See attached personnel code list.) 2. Review of the 2 TP records revealed no documentation of competency assessments performed by the lab director in 2017. The inspector requested the competency assessments for the TP A and TP B. The documentation was unavailable for review. 3. Review of the QA policy revealed the following statement: "The Laboratory Director will use personal observations to perform ongoing assessment of all employees of the laboratory to ensure competence of job performance. At least annually, the Director should review performance and provide a written review to be

	filed in the individual's personnel file." 4. In an interview at approximately 11:00 AM, the laboratory nurse manager confirmed that the technical consultant failed to perform the competency assessments in 2017.