

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D1027317	(X3) Date Survey Completed 04/27/2021
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 on-site CLIA recertification survey was conducted at Haymarket Pediatrics, PLC on April 27, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on March 19, 2021 and virtual record review conducted on April 22, 2021. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiency is as follows: The inspector noted Haymarket Pediatrics, PLC performs SARS-CoV-2 (COVID-19) testing and was in compliance with the applicable COVID-19 reporting requirements.
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's Urine Culture Log, Individualized Quality Control Plan (IQCP) and interview, the laboratory failed to ensure the "Uri-Tek" media utilized for urine cultures were within manufacturer's expiration date while culturing nine (9) patient urine specimens from April 4, 2019 until April 22, 2019. Findings include: 1. A review of the laboratory's "Urine Culture log" from January 2019 until April 27, 2021 revealed the laboratory utilized Uri-Tek media lot number 8H01A exp 4-01-19 to perform 9 urine cultures on the following days after expiration: 04/04/2019-1 patient; 04/05/2019-1 patient; 04/10/2019-2 patients; 04/15/2019-1 patient; 04/16/2019-1 patient; 04/17/2019-1 patient; 04/18/2019-1 patient; 04/22/2019-1 patient. A total of 9 patient urine specimens were cultured with Uri-Tek media lot number 8H01A exp 4-01-19. There were no other lot numbers of Uri-Tek media listed as utilized from April 4, 2019 until April 22, 2019. The surveyor requested documentation of additional lot numbers of Uri-Tek media utilized from April 4, 2019</p>

until April 22, 2019. The laboratory provided no additional documentation. 2. A review of the laboratory's IQCP for the Uri-Tek media revealed the statement: "Do not use after expiration date." 3. In an virtual interview with the lead nurse on April 22, 2021 at approximately 10:10 AM, the findings were confirmed.