Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0225145	09/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Blue Ridge Pediatric Assoc, Ltd	337 Westside Station Drive, Winchester, 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 Blue Ridge Pediatric Assoc., LTD on September 12, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies 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, Quality Control (QC) Logs and interviews, the laboratory failed to monitor and evaluate analytic quality by failure to: perform visual checks, sterility checks and ability to support and inhibit growth for Orion Diagnositca Uricult Paddle agar from February 13, 2018 to September 12, 2019 (Cross Reference D 5477 A Repeat Deficiency); and document the ability to support and inhibit growth for HealthLink Strep Select agar from February 5, 2018 to September 12, 2019 (Cross Reference D 5477 B Repeat Deficiency).
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:
A. Based on review of the laboratory's Quality Control (QC) logs, patient urine culture logs, and interviews with Laboratory Director (LD), the laboratory failed to document each shipment of Orion Diagnostica Uricult Culture Paddle Agar media's visual checks, sterility checks, and ability to support and inhibit growth from February 13, 2018 to September 10, 2019 while reporting eighty-seven (87) patient urine cultures. Findings include: 1. In a discussion with the Laboratory Director at approximately 9:15 AM, the Laboratory Director stated that he/she had performed the ability to support and inhibit growth for the Uricult Paddles one time since the last inspection. 2. Review of the laboratory's Quality Control records for the Orion Diagnostica Uricult Culture Paddle Agar from January 2018 until the date of the survey on September 12, 2019 revealed documentation of the Uricult visual checks, sterility checks and ability to support and inhibit growth on January 23, 2018 for Lot Number 1798597, expiration date 6/18/18. A new shipment of Uricult paddles was documented as received on February 13, 2018. No further documentation of the subsequent shipments of the Uricult lot numbers, received dates, visual checks, sterility checks and ability to support and inhibit growth was observed. The surveyor requested to review the laboratory's QC log sheets with the lot numbers, received dates, visual checks, sterility checks and ability to support and inhibit growth for the Uricult utilized for patient testing from February 13, 2018 until the date of the survey on September 12, 2019. The laboratory provided no documentation of the Uricult lot numbers, received dates, visual checks, sterility checks and ability to support and inhibit growth to review. 3. Review of the laboratory's patient urine culture logs from February 13, 2018 to the date of the survey on September 12, 2019 revealed 87 patient urine cultures were reported utilizing the Orion Diagnostica Uricult Paddles. 4. In an exit interview with the LD at approximately 11:45 AM, the LD confirmed the findings. This is a REPEAT DEFICIENCY. B. Based on review of the laboratory's Quality Control (QC) logs, patient throat culture logs, and interview with Laboratory Director (LD), the laboratory failed to document the ability to support and inhibit growth for twenty-seven (27) of twenty-eight (28) shipments of Strep Select media received from January 29, 2018 to the date of the survey on September 12, 2019 while reporting two hundred forty (240) patient throat cultures. Findings include: 1. Review of the laboratory's throat culture QC logs from January 25, 2018 until the date of the survey on September 12, 2019 revealed a shipment of HealthLink Strep Select Agar, lot 1728901 received date January 25, 2018, with documented ability to support and inhibit growth. The following lot numbers and received dates of Strep Select agar utilized for patient testing were logged in the QC log with no documentation of the shipment of the agar's ability to support and inhibit growth: Lot number 1728901, received 02/05/18; Lot number 1728901, received 03/15/18; Lot number 1728901, received 03/29/18; Lot number 1804607, received 04/09/18; Lot number 1804607, received 05/07/18; Lot number 1804607, received 05/14/18; Lot number 1805300, received 05/29/18; Lot number 1805300, received 06/13/18; Lot number 1811400, received 06/30/18; Lot number 1811400, received 07/27/18; Lot number 1817008, received 09/04/18; Lot number 1817008, received 09/24/18; Lot number 1819108, received 10/01/18; Lot number 1827400, received 10/12/18; Lot number 1827400, received 11/14/18; Lot number 1827400, received 12/14/18; Lot number 1830506, received 01/10/19; Lot number 1830506, received 01/29/19; Lot number 1833805,

	received 02/07/19; Lot number 1833805, received 02/28/19; Lot number 1902300, received 03/22/19; Lot number 1902300, received 04/09/19; Lot number 1905708, received 04/16/19; Lot number 1905708, received 05/14/19; Lot number 1908409, received 06/05/19; Lot number 1908409, received 06/24/19;and Lot number 4412190, received 08/02/19. A total of 27 shipments of Strep Select agar with no documentation of the agar's ability to support and inhibit growth. The surveyor requested to review the laboratory's QC log sheets for the lot numbers of Strep Select agar received and utilized for patient testing from February 5, 2018 until the date of the survey on September 12, 2019. The laboratory provided no documentation of the 27 shipments of Strep Select agar's ability to support and inhibit growth to review. 2. Review of the laboratory's patient throat culture logs from February 5, 2018 until the date of the survey on September 12, 2019 revealed that 240 patient cultures were reported utilizing Strep Select Agar. 3. In an exit interview with the LD at approximately 11:45 AM, the LD confirmed the findings. **This is a REPEAT DEFICIENCY.