Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0680982	09/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Anderson Hills Pediatrics Inc	1126 West Ohio Pike, Amelia, OH	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on document review, direct observation and an interview with Testing Personnel (TP#12), laboratory personnel failed to follow the written procedure manual for specimen processing with one out of one specimens. This deficient practice had the potential to affect all patients tested under the subspecialty of bacteriology on 09/17/2019. Findings include: 1. Review of the laboratory policy titled "Anderson Hills Pediatrics Quality Assurance", approved by the Laboratory Director 05/12/2014 found the following statement: "...All specimens must be properly identified when they are collected with the patient name and chart number." 2. Direct observation of the laboratory on 09/17/2019 at 11:34 AM found one urine specimen cup labeled with only the patient's first name. The urine specimen cup indicated above lacked the patient's full name and chart number as required per the laboratory's protocol. 3. TP #12 confirmed the urine specimen cup had been labeled incorrectly. The interview occurred on 09/17/2019 at 11:35 AM.
D5789	TEST RECORDS CFR(s): 493.1283(b) Records of patient testing including, if applicable, instrument printouts, must be retained.

	This STANDARD is not met as evidenced by: Based on review of the Illumegene instrument printouts and interviews with the Laboratory Director (LD) and Testing Personnel (TP#12), the laboratory failed to retain group Streptococcus A (Strep A), instrument printouts. This deficient practice had the potential to affect all patients tested under the subspecialty of bacteriology. Findings Include: 1. The surveyor requested the laboratory's Illumigene analyzer instrument printouts for patient testing for 2018 through 2019 from TP#12. TP#12 provided one instrument printout dated 09/16/2019 time stamped 2:58 PM. 2. TP#12 and the LD stated the laboratory throws away the Illumigene patient test printouts after the data has been transcribed into the electronic medical record and could not provide the requested documents. The interviews occurred on 09/17/2019 at 11:00 AM.