

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2184612	(X3) Date Survey Completed 10/07/2020
Name of Provider or Supplier Allora Laboratory, Llc	Street Address, City, State 405 St Johns Church Rd, Suite 104, Camp Hill, PA	
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
D6086	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by: Based on review of policies and procedures, lack of documentation and interview with the Laboratory Director (LD) and Technical Supervisor (TS), the laboratory failed to establish and document a program for the prevention of carry-over specimens for 3 of 3 chemistry analyzers (Pentra C400, Access 2 and DCA Vantage) that perform both veterinary and human testing from 7/15/2020 to the date of survey. Findings include: 1. On the day of survey, 10/07/2020, the LD could not provide a policy or procedure that reviews how to prevent carry-over for 3 of 3 chemistry analyzers that are use to perform veterinary and human specimens from 7/15/2020 to 10/07/2020. 2. On 7/15 /2020, the laboratory performed 1 human specimen and 2 feline specimens on the Pentra C400. 3. The LD and TS Confirmed the findings above on 10/07/2020 at 12:00 p.m.</p>