

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D2183478	(X3) Date Survey Completed 10/14/2022
Name of Provider or Supplier National Veterinary Services Laboratories	Street Address, City, State 1920 Dayton Avenue, Ames, IA	
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on lack of viral transport media records and confirmed by laboratory personnel identifier #6 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 10/14/2022, the laboratory failed to retain records for viral transport media prepared in the laboratory, including lot numbers, expiration dates, quality control, and sterility checks for all media prepared from 04/30/2021- 10/14/2022. At the time of the survey, personnel identifier #6 confirmed that the laboratory did not have records for the viral transport media produced and used from 04/30/2021- 10/14/2022.</p>
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 performance specification records for the Taqpath COVID-19 Combo Kit and confirmed by personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 9:00 am on 10/10/2022, the laboratory director failed to ensure that the procedures for verification of performance specifications are adequate to determine the accuracy and precision for the Taqpath COVID-19 Combo</p>

Kit from 05/01/2022- 10/14/2022. The findings include: 1. The laboratory verified performance specifications for the Taqpath COVID-19 Combo Kit in May 2022. 2. Review of performance specification data indicated that an analysis of the raw data for accuracy determination had not been performed. In addition, the laboratory did not verify the performance specification of precision. 3. At the time of the survey, personnel identifier #2 confirmed that the laboratory director failed to ensure that the procedures for the verification of the performance specifications, accuracy and precision, are adequate. Personnel identifier #2 also confirmed that the records had not been reviewed by the laboratory director.