Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2184183	01/18/2022
Name of Provider or Supplier	**Street Address, City, State**	
Texas A&M Veterinary Diagnostic Laboratory (Tvmdl)	3209 Russell Long Boulevard, Canyon, TX	

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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Review of the manufacturer's instructions, CMS 116, patient reports and interview of facility personnel found the laboratory failed to follow the manufacturer's instructions for disseminating all authorized fact sheets when using the Thermo Fisher COVID-19 Combo Kit and TaqPath COVID-19 Advanced for patient testing in 2020 and 2021. The findings included: 1. Review of the manufacturer's instructions found under the heading CONDITIONS OF AUTHORIZATION FOR LABORATORY " Authorized laboratories using the COVID-19 Combo Kit and the TaqPath COVID-19 Advanced must include with result reports of the COVID-19 Combo Kit and TaqPath COVID-19 Advanced , all authorized Fact Sheets." 2. Review of the CMS 116 found the laboratory recorded an annual volume of 25,116 Covid tests performed. 3. Review of patient reports found the laboratory did not include instructions to providers on where to obtain the fact sheets or included copies of the authorized fact sheets. 4. Interview of the General Supervisor on the CMS report 209 Laboratory Personnel Report conducted on January 18, 2022 at 11:59 AM confirmed that the laboratory did not include the authorized Fact Sheets with the patient test results for COVID-19.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification,

	either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Review of patient test reports and interview of facility personnel found that the laboratory failed to ensure that the final test report included the address of the facility where testing was performed on eight of eight reports reviewed . Findings included: 1. Review of 8 patient test reports found that the final report did not include the address of the laboratory were patient testing was done. 2. Interview of the General Supervisor listed on the CMS report 209 laboratory personnel report conducted on January 18, 2022 at2:31 PM confirmed that the laboratory address was not on the report.