Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0222887	12/14/2020
Name of Provider or Supplier	**Street Address, City, State**	
United Medical Laboratories Inc	1980 Gallows Rd - Suite 300, Vienna, 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 unannounced, on-site CLIA complaint survey was conducted at United Medical Labs, INC on December 2, 2020 and off-site investigation from December 2, 2020 to December 14, 2020 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:
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, lack of documentation, patient testing logs and interviews, the laboratory failed to provide instructions for the collection and handling of patient nasopharyngeal (NP) specimens for COVID-19 Polymerase Chain Reaction (PCR) testing from November 3, 2020 until December 2, 2020 (the date of the onsite investigation). The findings include: 1. A review of the laboratory's patient test logs revealed the laboratory began COVID-19 PCR testing on November 3, 2020. 2. Review of the laboratory's policies and procedures revealed a lack of instructions for the collection and handling of patient nasal NP specimens for COVID-19 PCR testing. The surveyor requested a copy of the laboratory's instructions for the collection and handling of patient nasal NP specimens for COVID-19 PCR testing. The laboratory provided no instructions for review. 3. In an interview with the Administrative Supervisor and Testing Personnel, on December 2, 2020 at approximately 11:00 AM, the findings were confirmed.
D5815	TEST REPORT CFR(s): 493.1291(h)

	When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, lack of documentation, patient testing logs and interviews, the laboratory failed to establish turnaround times and method of notification of delayed reporting of results for COVID-19 Polymerase Chain Reaction (PCR) testing from November 3, 2020 until December 2, 2020 (the date of the onsite investigation). Findings include: 1. A review of the laboratory's patient test logs revealed the laboratory began COVID-19 PCR testing on November 3, 2020. 2. Review of the laboratory's policies and procedures revealed a lack of a policy for the establishment of turnaround times and method of notification of delayed reporting of results for COVID-19 Polymerase Chain Reaction (PCR) testing from November 3, 2020 until December 2, 2020 (the date of the onsite investigation). The surveyor requested a copy of the laboratory's policy for the establishment of turnaround times and method of notification of delayed reporting of results for COVID-19 Polymerase Chain Reaction (PCR) testing. The laboratory provided no policy for review. 3. In an interview with the Administrative Supervisor and Testing Personnel on December 2, 2020 at approximately 11:00 AM, the findings were confirmed.