Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2215228	09/14/2021
Name of Provider or Supplier	**Street Address, City, State**	
Signature Diagnostics	1501 Preble Avenue, Suite 200, Pittsburgh, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory competency assessment policy and interview with the technical supervisor (TS) and laboratory director (LD), the laboratory failed to establish a competency assessment procedure to assess 1 of 1 TS/general supervisor (GS) for competency in 2021. Findings include: 1. On the day of survey, 09/14/2021, the laboratory could not provide a written policy that reviews how to assess the competency for 1 of 1 TS/GS in 2021. 3. The TS and LD confirmed the findings above on 09/14/2021 around 11:15 am.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with the technical supervisor (TS) and laboratory director (LD), the laboratory failed to provide written or electronic test requests from an authorized person for SAR-CoV-2 testing performed on the Thermofisher QuantStudio 5 Real-Time PCR System in 2021. Finding Include: 1. On the day of survey, 09/14/2021, the laboratory could not provide written or electronic tests request from an authorized person for SAR-CoV-2

	testing performed on the Thermofisher QuantStudio 5 Real-Time PCR System in 2021. 2. The laboratory could not provide a test request or standing order policy. 3. The TS and LD confirmed the findings above on 09/14/2021 around 12:10 pm.
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 review of the laboratory procedure manual and interview with the technical supervisor (TS) and laboratory director (LD), the laboratory failed to establish a procedure for reporting positive and negative SARS-CoV-2 testing to the appropriate health agencies as required from 07/14/2021 to the day of survey. Findings include: 1. On the day of survey, 09/14/2021, the laboratory could not provide a procedure for reporting positive and negative SARS-CoV-2 testing to the appropriate health agencies as required from 07/14/2021 to 09/14/2021. 2. 476 specimens were analyzed for SARS-CoV-2 from 07/14/2021 to 09/14/2021. 3. The TS and LD confirmed the findings above on 09/14/2021 around 12:00 pm.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of temperature records and interview with the laboratory director (LD) and technical supervisor (TS), the laboratory failed to monitor the room temperature for 3 of 4 rooms where SAR- CoV-2 testing was performed from 07/14 /2021 to the day of survey. Findings Include: 1. On the day of survey, 09/14/2021, review of the laboratory temperature records revealed, 3 of 4 rooms were not monitored for temperature where SAR- CoV-2 testing was performed from 07/14 /2021 to 09/14/2021. 2. The LD and TS confirmed the findings about on 09/14/2021 around 12:50 pm.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g)

	The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of records, lack of documentation and interview with the technical supervisor (TS) and laboratory director (LD), the laboratory failed to document quality control (QC) performed each day of patient testing on the Thermofisher QuantStudio 5 Real-Time PCR System used to analyze SAR-CoV-2 from 07/14/2021 to the day of survey. Findings include: 1. On the days of survey, 09/14/2021, the laboratory could not provide documentation of QC performed each day of patent testing on the Thermofisher QuantStudio 5 Real-Time PCR System used to analyze SAR-CoV-2 from 07/14/2021 to 09/14/2021. 2. From 07/14/2021 to 09/14/2021 the laboratory analyzed 476 SAR-CoV-2 patient specimens. 3. The TS and LD confirmed the findings above on 09/14/2021 around 12:10 pm.