Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2204746	10/07/2021
Name of Provider or Supplier	**Street Address, City, State**	
Encore Diagnostics Llc	31200 Mound Rd Suite 101c, Warren, MI	

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
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 record review and interview with the Laboratory Liaison (LL), the laboratory failed to have a written request for the SARS-CoV-2 (COVID-19) Qualitative Polymerase Chain Reaction (PCR) testing from an authorized person for 3 (#4931, #243, and #235) of 27 patient test results audited. Findings include: 1. Record review for 3 of 27 patient SARS-CoV-2 (COVID-19) Qualitative PCR test results revealed the requisitions were not signed by an authorized person to order the tests as follows: a. Patient #4931 - ordered on 01/10/2021 b. Patient #243 - ordered on 08/05 /2021 c. Patient #235 - ordered on 09/16/2021 2. During a phone interview on 10/06 /2021 at 4:23 pm, the LL confirmed the laboratory did not have written requests for patient testing.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by:

	. Based on record review and interviews, the laboratory failed to meet applicable analytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to label reagents used in virology testing with the name, date of reconstitution, date of expiration, and storage requirements. Refer to D5415. 2. The laboratory failed to establish performance specifications for the use of an automated nucleic acid extraction method and a Real-Time PCR method not specified in the Emergency Use Authorization. Refer to D5423. 3. The laboratory failed to perform and document the function checks as required by the manufacturer for the IVYX Scientific Micropipettes. Refer to D5431.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with a Testing Personnel, the laboratory failed to label reagents used in virology testing with the name, date of reconstitution, date of expiration, and storage requirements for 2 of 2 unlabeled bottles, one in the extraction room and one in the amplification room were observed. Findings include: 1. An observation by the surveyor on 10/06/2021 at approximately 9: 30 am revealed 2 reagent bottles used in virology testing, next to the hood in the amplification room and the extraction room unlabeled. 2. A review of the laboratory's "NCCLS Physician's Office Laboratory Procedure Manual Vol. 22 No 7" on page 36 a procedure for Internal Quality Control titled "Reagent" revealed "All reagents are not to be labeled with the date of reconstitution, date of expiration (if indicated, storage requirements, and initialed by person preparing reagent)." 3. An interview on 10/06 /2021 at approximately 9:30 am with a Testing Personnel confirmed the bottles had not been labeled.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Liaison (LL), the laboratory failed to establish performance specifications for the use of an automated

	nucleic acid extraction method and a Real-Time Polymerase Chain Reaction (PCR) method not specified in the Emergency Use Authorization prior to testing patients for 9 (01/11/2021 to 10/06/2021) of 9 months of testing. Findings include: 1. A tour of the laboratory performed on 10/06/21 at 9:00 am revealed a Bioneer extraction instrument, a QuantStudio 5 PCR instrument, and a ExpiPrep 96 Lite DNA/RNA prep kit. 2. A review of the laboratory's Instructions for Use (IFU) document titled "GeneFinder COVID-19 Plus RealAmp Kit" revealed the extraction kit, the Bioneer extraction instrument, and the QuantStudio 5 Real-Time PCR instruments in use were not listed in the IFU. 3. On 10/06/2021 at approximately 10:15 am the surveyor requested the performance specifications for the test system. The surveyor received a "Correlation Study" between two labs which revealed it did not contain the following elements of a performance specifications for test systems without FDA approval or modified FDA-cleared or approved test systems: a. Precision - reproducibility b. Analytical sensitivity c. Analytical specificity to include interfering substances d. Reportable Range 4. A review of testing records revealed patient testing started on 1 /11/2021 and that 63,991 patients have been tested as of 9/24/2021. 5. During a phone interview on 10/06/2021 at 4:23 pm, the LL confirmed the laboratory was using a test system not listed in the IFU and the laboratory did not validate prior to patient testing.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: . Based on observation and interview with Laboratory Liaison (LL), the laboratory failed to perform and document the function checks as required by the manufacturer for the IVYX Scientific Micropipettes for 10 of 10 pipettes for 9 (01/11/2021 to 10/06 /2021) of 9 months of use. Findings include: 1. During a tour of the laboratory on 10 /06/2021 at 9:00 am, the surveyor noticed a pipette stand in the extraction room with 5 pipettes and a stand in the amplification room with 5 pipettes. 2. A review of the "IVYX Scientific Micropipette Users Manual" under Section 9 "Maintenance" revealed in a note "Check the performance of your pipette regularly e.g. every 3 months and always after in-house service or maintenance." 3. A review of the "Laboratory Procedure Manual" revealed a lack of documentation for the pipette maintenance and/or recalibrating and a procedure to follow. 4. During a phone interview on 10/06/2021 at 4:23 pm, the LL confirmed there was no documentation of pipette maintenance and/or calibrations and no policy or procedure.