Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2224771	08/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Encompass Laboratory Llc	2323 S Voss Rd, Unit 455, Houston, 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
D0000	An announced initial survey was performed on 8/8/2022-8/9/2022 The laboratory was found out of compliance with the CLIA regulations. The condition not met was: D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems; Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's records, and confirmed in an interview found the laboratory failed to identify, monitor, and correct problems in pre-analytic systems as evidenced by: 1. The laboratory failed to ensure the receiving temperature was maintained at 2-8C per the manufacturer's instructions during transport for COVID-19 test on one of one Biorad CFX 96 Touch System. Refer to D5311A. 2. The laboratory failed to follow the manufacturer's instructions to perform patient specimens of 72 hours at 2-8C for 10 of 20 patients reviewed from April to July 2022 for COVID-19 test on one of one Biorad CFX 96 Touch System. Refer to D5311B.
D5305	TEST REQUEST CFR(s): 493.1241(c)

	The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on a random review of patient test requisitions and staff interview, it was revealed that the laboratory failed to ensure the specimen's collection date and time were included on the Covid test requisitions for 13 of 20 patient's test requisitions reviewed from April to August 2022. Findings include: 1. A random review of the laboratory's Covid test requisitions from patients tested between April to August 2022 revealed the following 13 requisitions failed to include the specimen's collection date and time: Patient: LP03231953 Patient: SE01281963 Patient: MS01121951 Patient: JH05041956 Patient: CH07171957 Patient: MO10071958 Patient: CS11301966 Patient: KH11281955 Patient: TJ09021950 Patient: CJ10301974 Patient: PH06241945 Patient: RB10241962 Patient: RG07231976 2. An interview with the technical supervisor on 8/9/22 at 11:20 a.m. in the storage room, after review of the records, confirmed the above findings.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: A. Based on the review of the laboratory's patient reports, policies, and records, the manufacturer's instructions, and confirmed in the interview found the laboratory failed to to ensure the temperature was maintained at 2-8C per manufacturer's instructions during transport for one of one Covid test: lumiraDx SARS-CoV-2 on the Biorad CFX 96 Touch System. The findings were: 1. Review of the laboratory records revealed the laboratory used the following. Swab used was Puritan PurFlock Ultra Sterile Flocked Collection Device (Ref: 25-3317-U; Lot#:S0059; Expiration date: 2026-05-01) Transport Media used was Filtrous Viraport (Catalog#: COV-30-3015-K1; Lot#: FD220208Y; Expiration date: 02-2023) 2. Review the Laboratory's records revealed the laboratory used EUA approved lumiraDx SARS-CoV-2 RNA STAR Complete test for COVID-19 test on one of one Biorad CFX 96 Touch System (SN:

785BR21753) 3. Review of the lumiraDx SARS-CoV-2 RNA STAR Complete instructions for use (SD-COM-ART-00046 Rev. 2 July 2021) under 8. Specimen Collection, Handling, and Storage revealed "8.2 Transporting Specimens ...If wet swab is expressed in a compatible buffer (...) store specimens at 2 to 8C for up to 72 hours after collection. If a delay in testing or shipping is expected, store specimens at -70C or below and ship on dry ice." 4. An interview with the general supervisor on 8/8 /2022 at 9:45 am in the accession area stated the patient specimens transport in a FedEx box with an ice pack. However, the facility does not monitor the temperature during or after receipt of patient specimens per manufacturer's instructions. 5. Review the laboratory's patient reports revealed the laboratory performs COVID-19 test with lumiraDx SARS-CoV-2 RNA started in April 2022. 6. Random review of patient test records from April to August 2022 revealed 10 patient specimens did not have documentation of receiving temperature per the manufacturer's requirements: Patient: SA01101958 Patient: DY03141963 Patient: JC09111953 Patient: SN04281950 Patient: MS01121951 Patient: LD09221944 Patient: EE11281962 Patient: DY03141963 Patient: BC11201945 Patient: TC12291954 7. An interview the technical supervisor on 8/8/22 at 12:40 pm in the office confirmed the facility did not monitor the temperature during or after receipt of patient samples. 8. Review of the laboratory's policy titled Pre-Analytic Policy (Document# GEN 20066) under II. Specimen Collection & Handling revealed the policy did not have written or establish policy for patient specimens transportation temperature requirements according to the manufacturer's instructions. Key: EUA=Emergency Use Authorization B. Based on the review of the EUA approved lumiraDx SARS-CoV-2 RNA STAR Complete test instructions for use, the laboratory's policies, patient records, and confirmed in an interview found that the laboratory failed to follow the manufacturer's instructions to perform patient specimens of 72 hours at 2-8C for 10 of 20 patient reports reviewed from April to July 2022 for EUA approved lumiraDx SARS-CoV-2 RNA STAR Complete test for COVID-19 test on one of one Biorad CFX 96 Touch System. The findings were: 1. Review the Laboratory's records revealed the laboratory used EUA approved lumiraDx SARS-CoV-2 RNA STAR Complete test for COVID-19 test on one of one Biorad CFX 96 Touch System (SN:785BR21753) started in April 2022. 2. Review of the lumiraDx SARS-CoV-2 RNA STAR Complete instructions for use (SD-COM-ART-00046 Rev. 2 July 2021) under 8. Specimen Collection, Handling, and Storage revealed "8.2 Transporting Specimens ...If wet swab is expressed in a compatible buffer (...) store specimens at 2 to 8C for up to 72 hours after collection. If a delay in testing or shipping is expected, store specimens at -70C or below and ship on dry ice." 3. Review of the laboratory's verification studies revealed no documentation of preanalytical studies beyond the 72 hours. (Cross refer to D5423) 4. Random review of the laboratory's patient records revealed the laboratory failed to perform testing within the 72 hours per manufacturer's instructions for 10 patient records reviewed. Patient: SA01101958 Collection date: 4/8/22 13:00 Received date: 4 /18/22 12:00 Elapsed time: 239 hours Patient: DY03141963 Collection date: 4/8/22 11:30 Received date: 4/18/22 12:00 Elapsed time: 240 hours Patient: JC09111953 Collection date: 5/5/22 14:45 Received date: 5/10/22 10:30 Elapsed time: 115 hours Patient: SN04281950 Collection date: 5/26/22 15:15 Received date: 5/31/22 11:30 Elapsed time: 116 hours Patient: MS01121951 Collection date: 5/27/22 16:00 Received date: 5/31/22 11:30 Elapsed time: 91 hours Patient: LD09221944 Collection date: 5/27/22 15:00 Received date: 5/31/22 11:30 Elapsed time: 92 hours Patient: EE11281962 Collection date: 6/10/22 10:35 Received date: 6/14/22 16:00 Elapsed time: 101 hours Patient: DY03141963 Collection date: 6/17/22 13:25 Received date: 6 /21/22 14:15 Elapsed time: 96 hours Patient: BC11201945 Collection date: 7/8/22 11: 30 Received date: 7/15/22 13:00 Elapsed time: 170 hours Patient: TC12291954 Collection date: 7/11/22 10:00 Received date: 7/15/22 13:15 Elapsed time: 99 hours 5.

	An interview with the technical supervisor on 8/9/22 at 11:25 a.m. in the storage room confirmed the above findings. Key: EUA=Emergency Use Authorization
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 the review the manufacturer's instructions, the laboratory's client service manual and confirmed in an interview found the laboratory failed to establish a client service manual with acceptability and rejection criteria to include requirements per the manufacturer's instructions. The findings were: 1. Review the Laboratory's records revealed the laboratory used EUA approved lumiraDx SARS-CoV-2 RNA STAR Complete test for COVID-19 test on one of one Biorad CFX 96 Touch System (SN: 785BR21753) 2. Review of the lumiraDx SARS-CoV-2 RNA STAR Complete instructions for use (SD-COM-ART-00046 Rev. 2 July 2021) under 8. Specimen Collection, Handling, and Storage revealed "8.2 Transporting Specimens ...If wet swab is expressed in a compatible buffer (...) store specimens at 2 to 8C for up to 72 hours after collection. If a delay in testing or shipping is expected, store specimens at -70C or below and ship on dry ice." 3. Review of the laboratory's client service manual titled Specimen Collection and Handling (Document#: GEN.2003) revealed no documentation provided to the clients of stored temperature of 2-8C after collection and sample stability for up to 72 hours per the manufacturer's instructions. 4, An interview with the technical supervisor on 8/9/22 at 11:25 a.m. in the storage room confirmed the above findings.
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 the review of the manufacturer's instructions, the laboratory's records, patient reports, and confirmed in an interview found the laboratory failed to document pre-analytical studies for one of one modified EUA approved covid test: lumiraDx SARS-CoV-2 RNA STAR Complete test. The findings were: 1. Review the Laboratory's records revealed the laboratory used EUA approved lumiraDx SARS-CoV-2 RNA STAR Complete test for COVID-19 test on one of one Biorad CFX 96 Touch System (SN:785BR21753). 2. Review of the lumiraDx SARS-CoV-2 RNA

	STAR Complete instructions for use (SD-COM-ART-00046 Rev. 2 July 2021) under 8. Specimen Collection, Handling, and Storage revealed "8.2 Transporting Specimens ...If wet swab is expressed in a compatible buffer (...) store specimens at 2 to 8C for up to 72 hours after collection. If a delay in testing or shipping is expected, store specimens at -70C or below and ship on dry ice." 3. Review of the laboratory records revealed the laboratory used Filtrous Viraport (Catalog#: COV-30-3015-K1; Lot#: FD220208Y; Expiration date: 02-2023) as Viral Transport Media (VTM) that is not listed as a compatible transport media per manufacturer's instructions. 4. Random review of patient test records from April to August 2022 revealed 10 of 20 patient reports reviewed were processed past the specimen stability of 72 hours per the manufacturer's requirements: Patient: SA01101958 Collection date: 4/8/22 13:00 Received date: 4/18/22 12:00 Elapsed time: 239 hours Patient: DY03141963 Collection date: 4/8/22 11:30 Received date: 4/18/22 12:00 Elapsed time: 240 hours Patient: JC09111953 Collection date: 5/5/22 14:45 Received date: 5/10/22 10:30 Elapsed time: 115 hours Patient: SN04281950 Collection date: 5/26/22 15:15 Received date: 5/31/22 11:30 Elapsed time: 116 hours Patient: MS01121951 Collection date: 5/27/22 16:00 Received date: 5/31/22 11:30 Elapsed time: 91 hours Patient: LD09221944 Collection date: 5/27/22 15:00 Received date: 5/31/22 11:30 Elapsed time: 92 hours Patient: EE11281962 Collection date: 6/10/22 10:35 Received date: 6/14/22 16:00 Elapsed time: 101 hours Patient: DY03141963 Collection date: 6 /17/22 13:25 Received date: 6/21/22 14:15 Elapsed time: 96 hours Patient: BC11201945 Collection date: 7/8/22 11:30 Received date: 7/15/22 13:00 Elapsed time: 170 hours Patient: TC12291954 Collection date: 7/11/22 10:00 Received date: 7 /15/22 13:15 Elapsed time: 99 hours 5. An interview the technical supervisor on 8/8 /22 at 12:45 pm in the office confirmed the above findings.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on a review of the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure preanalytic systems were followed to ensure quality testing. Findings include: 1. The laboratory failed to ensure the specimen's collection date and time were included on the Covid test requisitions. (refer to D5305) 2. The laboratory failed to to ensure the temperature was maintained at 2-8C per manufacturer's instructions during transport for the lumiraDx SARS-CoV-2 on the Biorad CFX 96 Touch System. (refer to D5311 A) 3. The laboratory failed to follow the manufacturer's instructions of performing patient specimen testing within 72 hours at 2-8C using the lumiraDx SARS-CoV-2 RNA STAR Complete test. (refer to D5311 B)