

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2237799	(X3) Date Survey Completed 07/15/2022
Name of Provider or Supplier Align Laboratories Llc	Street Address, City, State 3926 Barron St, Suite C107, Metairie, LA	
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 Initial survey was performed at Align Laboratories, LLC, CLIA # 19D2237799, on July 14, 2022 through July 15, 2022. Align Laboratories, LLC was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1441 CONDITION: Laboratories performing high complexity testing; Laboratory Director
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, personnel records, and interview with personnel, the laboratory failed to establish written policies and procedures to assess competency of laboratory personnel. Findings: 1. Review of the laboratory's policies and personnel records revealed the laboratory did not include frequency of performance of competency assessments and a written policy that included the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting of test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. Further review of the laboratory's policies revealed the laboratory did not include a written procedure that included, but not limited to,</p>

monitors assessed and frequency of performance for competency assessments for Technical Supervisor and General Supervisor. 3. In interview on July 14, 2022 at 11: 30 am the Technical Supervisor confirmed the laboratory did not have written policies related to competency assessments for laboratory personnel.

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's policy and procedure manual and interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include the following: a) Performance specification: detailed procedures for performing accuracy and precision (day-to-day, run-to-run, and within-run, as well as, operator variance), reportable and reference range studies, sensitivity, specificity, and actions to take when data from the studies fail to meet acceptability criteria b) Reporting SARS COV-2 results, to include, but not limited to procedure, who is responsible, and frequency of reporting c) Twice a year method/instrument comparison of test results for two (2) Quant Studio instruments d) Defined storage and temperature requirement for samples e) LIS check f) Monthly Quality Assurance sample test 2. In interview on July 14, 2022 at 10:04 am the Technical Supervisor stated the laboratory did not have a written procedure for reporting COVID results to the state. 3. In further interview on July 14, 2022 at 1:37 pm , the Technical Supervisor confirmed the laboratory's procedure manual did not include the identified policies.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's policies and interview with personnel, the laboratory failed to include detailed written procedures for Bacteriology testing. Findings: 1. In interview on July 14, 2022 at 9:12 am, the Technical Supervisor stated the laboratory utilizes tests provided by DNA Healthcare Solutions for respiratory, vaginal, urinary tract, and wound panel (Bacteriology) testing. The Technical Supervisor stated the laboratory had problems getting supplies for testing and started sending samples to a reference lab for testing as of June 28, 2022. 2. In further interview on July 14, 2022 at 10:25 am, the Technical Supervisor stated one (1) of the two (2) Quant Studio 12 K flex instruments, Quant Studio 1, was in use for respiratory, vaginal, urinary tract, and wound panel testing. 3. Review of the laboratory's standard operating procedures (SOP) for Bacteriology testing revealed the following information was not included: a) Cut-off value determined by the laboratory's validation was not indicated b) Information related to plates being pre-made by DNA Healthcare solutions and what reagents are included on the pre-made plates 4. In interview on July 15, 2022 at 9:33 am, the Technical Supervisor and Testing Personnel stated the plates are received from DNA Healthcare Solutions with the quality control, primers, probes, and mastermix included. The Technical Supervisor and Testing Personnel stated the laboratory staff adds patient samples to the pre-made plates. The Technical Supervisor and Testing Personnel confirmed the identified information was not specified/included in the laboratory's SOPs for Bacteriology testing.

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:
 I. Based on observation by surveyor, review of the laboratory's policies, validation studies, test menu, and interview with personnel, the laboratory failed to have complete precision studies for SARS COV-2 testing. Findings: 1. Observation by surveyor during the laboratory tour on July 14, 2022 revealed the laboratory utilizes two (2) Quant Studio 12 K flex instruments for SARS COV-2 testing. 2. Review of the laboratory's policies revealed the laboratory did not have a written procedure for performance specification studies. 3. Review of the laboratory's validation studies revealed the laboratory did not include operator variance for their precision study. 4. In interview on July 14, 2022 at 1:37 pm, the Technical Supervisor confirmed the laboratory did not include operator variance in their precision studies for SARS COV-2 testing. 5. Review of the laboratory's test menu revealed the laboratory performs 6,000 SARS COV-2 tests annually. II. Based on review of the laboratory's policies, validation studies, test menu, and interview with personnel, the laboratory failed to

have complete performance specification studies for Bacteriology testing. Findings: 1. In interview on July 14, 2022 at 9:12 am, the Technical Supervisor stated the laboratory utilizes tests provided by DNA Healthcare Solutions for respiratory, vaginal, urinary tract, and wound panel (Bacteriology) testing. The Technical Supervisor stated the laboratory had problems getting supplies for testing and started sending samples to a reference lab for testing as of June 28, 2022. 2. In further interview on July 14, 2022 at 10:25 am, the Technical Supervisor stated one (1) of the two (2) Quant Studio 12 K flex instruments, Quant Studio 1, was in use for respiratory, vaginal, urinary tract, and wound panel testing. 3. Review of the laboratory's validation studies for Bacteriology testing revealed the following studies were not included: a) Summary of validation procedure b) Acceptability criteria c) Raw data for accuracy, precision, reportable range, sensitivity, and specificity d) Specificity, to include interfering substances, what specific substances were used for studies 4. In interview on July 14, 2022 at 4:30 pm via telephone, the DNA Healthcare Solutions employee, who assisted with the validations, confirmed a written description /summary of what the laboratory did for each study, acceptability criteria, and specific interfering substances used for their validation was not included. 5. In interview on July 15, 2022 at 9:33 am, the Technical Supervisor confirmed the laboratory was unable to provide the raw data for the validation studies. III. Based on review of the laboratory's procedures, validation studies, and interview with personnel, the laboratory failed to establish specimen stability for Bacteriology testing. Findings: 1. In interview on July 14, 2022 at 9:12 am, the Technical Supervisor stated the laboratory utilizes tests provided by DNA Healthcare Solutions for respiratory, vaginal, urinary tract, and wound panel (Bacteriology) testing. The Technical Supervisor stated the laboratory had problems getting supplies for testing and started sending samples to a reference lab for testing as of June 28, 2022. 2. In further interview on July 14, 2022 at 10:25 am, the Technical Supervisor stated one (1) of the two (2) Quant Studio 12 K flex instruments, Quant Studio 1, was in use for respiratory, vaginal, urinary tract, and wound panel testing. 3. Review of the laboratory's extraction procedure revealed "Stability studies completed at reference laboratory." 4. In interview on July 14, 2022 at 4:21 pm the Technical Supervisor stated stability studies were not performed at or by the laboratory. The DNA Healthcare Solutions employee stated the stability studies performed were for the reagents not the specimen.

D5821

TEST REPORT
CFR(s): 493.1291(k)

When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.

This STANDARD is not met as evidenced by:
Based on review of patient test requisitions, patient final test reports, and interview with personnel, the laboratory failed to issue corrected reports for SARS COV-2 testing for four (4) patients reviewed. Findings: 1. Review of random selection of patient test requisitions revealed a "COVID-19 Rapid PCR" test was ordered for the following four (4) patients: a) Report Date: December 1, 2021: R213220052 b) Report Date: February 15, 2022: R220430207 c) Report Date: June 17, 2022: R221680012 d)

Report Date: July 1, 2022: R221820028 2. Review of the corresponding patient final test reports revealed a "COVID-19 PCR," molecular PCR test, not rapid, was performed and reported on the four (4) identified patients. 3. Further review of the four (4) patient final test reports revealed the following comment: "Mesa Biotech Accula SARS-CoV-2 RT-PCR. The Accula SARS-CoV-2 (Quantitative NAAT, Nucleic Acid, Endpoint) test is only for use under the food and drug administration's Emergency Use Authorization. A negative result means that the virus that causes COVID-19 infection (SARS-CoV-2) was not present in the specimen above the limit of detection of the assay. A negative result does not rule out the possibility of COVID-19 and should not be used as the sole basis for treatment or patient management decisions. Test results should be interpreted in conjunction with your medical history, clinical signs and symptoms and the result of the other diagnostic tests performed. If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing should be considered by healthcare providers in consultation with public health authorities." 4. Review of the patient final test reports revealed the laboratory did not have corrected reports for the identified four (4) patients. 5. In interview on July 14, 2022 at 3:22 pm, the Technical Supervisor stated their laboratory receives overflow samples from a local COVID testing center that performs the waived rapid tests. The Technical Supervisor stated their laboratory does not perform waived COVID tests, only the molecular COVID test. The Technical Supervisor stated the identified orders for rapid test were incorrect; the laboratory's order designation for molecular SARS COV-2 testing is "COVID-19 PCR N1 N2." The Technical Supervisor confirmed the laboratory did not send out corrected reports for the identified patients.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:
Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to meet the experience requirement for high complexity testing. Refer to D6078. 2. The Laboratory Director failed to establish complete performance specifications for testing. Refer to D6086. 3. The Laboratory Director failed to ensure final reports included required pertinent information. Refer to D6098. 4. The Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6103. 5. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6106.

D6078

LABORATORY DIRECTOR QUALIFICATIONS
CFR(s): 493.1443

The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory

director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b) (1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview with personnel, the Laboratory Director failed to meet the experience requirement for high complexity testing. Findings: 1. Review of personnel records for the Laboratory Director revealed the Laboratory Director had a Doctor of Osteopathy degree. The Laboratory Director did not have documentation of at least one (1) year of laboratory training during medical residency or at least two (2) years of experience directing or supervising high complexity testing. 2. In interview on July 14, 2022 at 1:37 pm, the Operations Specialist stated he thought the Laboratory Director was approved to serve as director. He further stated the employee who was in communication with Louisiana's CLIA Program Manager regarding the Laboratory Director is not longer employed with the company. The Operations Specialist confirmed the laboratory did not have documentation of the Laboratory Director meeting the experience requirement.

D6086

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to establish complete performance specifications for

	<p>testing. Findings: 1. The laboratory failed to have complete precision studies for SARS COV-2 testing. Refer to D5423 I. 2. The laboratory failed to have complete performance specification studies for Bacteriology testing. Refer to D5423 II. 3. The laboratory failed to establish specimen stability for Bacteriology testing. Refer to D5423 III.</p>
D6098	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8)</p> <p>The laboratory director must ensure that reports of test results include pertinent information required for interpretation.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure final reports included required pertinent information. Refer to D5821.</p>
D6103	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D5209.</p>
D6106	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to include detailed written procedures for Bacteriology testing. Refer to D5403.</p>
D6112	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451</p> <p>The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed</p>

basis to provide supervision as specified in (a) of this section.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Technical Supervisor failed to provide technical and scientific oversight for the laboratory. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to include detailed written procedures for Bacteriology testing. Refer to D5403. 3. The laboratory failed to issue corrected reports for SARS COV-2 testing for four (4) patients reviewed. Refer to D5821.

D6115

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(2)

The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, record review, and interview with personnel, the Technical Supervisor failed to ensure the laboratory established complete performance studies. Findings: 1. The laboratory failed to have complete precision studies for SARS COV-2 testing. Refer to D5423 I. 2. The laboratory failed to have complete performance specification studies for Bacteriology testing. Refer to D5423 II. 3. The laboratory failed to establish specimen stability for Bacteriology testing. Refer to D5423 III.