

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 41D2092190	(X3) Date Survey Completed 12/07/2018
Name of Provider or Supplier Alpha Labs, Inc	Street Address, City, State 1025 Waterman Ave, East Providence, RI	
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
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on the attached notice of determination of noncompliance, the laboratory did not meet state Law 23-16.2-6. The Rhode Island Department of Health took adverse action against the laboratory. See attached.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed monitor and document of refrigerator temperatures. Findings include: 1. Record review of the laboratory's "Daily Temperature Chart" logs for specimen storage on 12/7/18 revealed, no recorded specimen refrigerator temperatures for the months of November and December 2018 and no temperature charts available for the testing months of August and September 2018 2. Interview with the Laboratory Director (LD) on 12/7</p>

/18 at 11:00 a.m. revealed that technical staff failed to record temperature data for the clinical specimen refrigerator; in addition, the LD acknowledged that the quality assurance policy failed to identify and ensure correction of this oversight.

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review and staff interview the laboratory failed to document corrective actions. Findings include: 1. Record review of the laboratory's "Daily Temperature Chart" logs for specimen storage on 12/7/18 revealed, no recorded specimen refrigerator temperatures for the months of November and December 2018 and no temperature charts available for the testing months of August and September 2018 2. Interview with the Laboratory Director (LD) on 12/7/18 at 11:00 a.m. revealed that technical staff failed to record temperature data for the clinical specimen refrigerator; in addition, the LD acknowledged that the quality assurance policy failed to identify and ensure correction of this oversight.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on record review and staff interview the laboratory failed in ensure testing reports specified the name and address of all testing laboratories. Findings include: 1. Record review of Alpha Labs testing reports on 12/7/18 revealed that 5 of 5 final reports stated Alpha labs as the main testing facility but listed the address of Aria Diagnostics, LLC, 5635 W. 96th street, ste 300, Indianapolis, IN 46378. Which is unlicensed to perform testing in the state of Rhode Island. 2. Interview with the laboratory director on 12/7/18 at 11:00 a.m. revealed that the 60 patients tested at Alpha Labs have the same testing report format and listed a mix of Aria's address and

Alpha lab's name. 3. Interview with the chief operating officer (COO) on 12/7/18 at 11:00 a.m. revealed that Alpha Labs owns Aria laboratory and refers all samples coming through Alpha to Aria for testing.

D6024

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(7)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory director failed in administrative operations of the laboratory. Refer to D5781 Refer to D5413

D6026

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(8)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory director failed to ensure accurate test reporting. Refer to D5805

D6028

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(10)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

This STANDARD is not met as evidenced by:
Based on record review and staff interview the laboratory director failed to ensure personnel met compliance with applicable state regulations prior to testing patient samples. Refer to D3009 Refer to D6064

D6064

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(a)

Each individual performing moderate complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to employ qualified personnel who are licensed and/or certified per the standards of the Rhode Island general laws. Findings include: 1. Record review of R.I. Gen. Laws 23-16.2-6 on 12/7/18 revealed that: "The standards for qualification of personnel who perform clinical laboratory tests shall require, as a minimum, successful completion of a nationally recognized certification examination." 2. Record review of testing personnel training documentation on 12/7/18 revealed 2 of 2 testing personnel to have no nationally recognized examination documentation, certifications, or licenses. 2. Interview with the laboratory director on 12/7/18 at 11:00 a.m. revealed that the director was unaware that Rhode Island requires national certification examinations for clinical laboratory testing personnel.