Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2175145	03/29/2021
Name of Provider or Supplier	**Street Address, City, State**	
Greenwood Labs, Llc - Molecular Division	8907 Kanis Road, Suite 401, Rooms 2 And 3, Little Rock, AR	

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
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: Through observation, review of temperature records, lack of documentation and interview with laboratory staff it was determined that the laboratory failed to document proper storage temperatures in one of two refrigerators and two of three freezers in which reagents with storage temperature requirements were stored. Findings follow: A) In a tour of the laboratory on 3/29/21 at 09:30 AM refrigerator (a) and freezer (b) were observed in laboratory room (3) and freezer (c), freezer (d) and refrigerator (e) were observed in laboratory room (2). B) Review of laboratory temperature records revealed that temperature records for freezer (b) were not available from 3/16/20 to the date of the survey and records for freezer (d) and refrigerator (e) were not presented. C) In a tour of the laboratory on 3/29/21 at 01:00 PM the following items with storage temperature requirements were observed: In freezer (b) in laboratory room (3): * three boxes Magpik performance verification kit lot # B83087 temperature requirement -25 to -15 degrees C. * three boxes Magpik calibration kit lot # B81141 temperature requirement -25 to -15 degrees C. * fourteen boxes X-Tag Gastrointestinal Pathogen Panel lot # IK032C-0113 temperature requirement -25 to -15 degrees C. In freezer (d) in laboratory room (2) * Eight boxes X Tag Gastrointitestinal Panel lot 1K032C-0112 temperature requirement -25 to -15

	degrees C. * One box X Tag Gastrointestinal Panel lot 1K032C-0117 temperature requirement -25 to -15 degrees C. In refrigerator (e) in laboratory room (2) * Fifteen bottles of Nucligens Easy Mag Extraction Buffer lot # Z011KN3EB temperature requirement 2 to 8 degrees C D) Upon request, the laboratory could not produce temperature records for freezer (b) in laboratory room (3) or refrigerator (e) or freezer (d) in laboratory room (2) E) In an interview on 3/29/21 at 02:40 PM the laboratory staff member, identified as number three on the CMS 209 form, confirmed that temperature records for the freezers and refrigerator identified above were not available.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Through observations made during a tour of the laboratory and interview with laboratory staff, it was determined the laboratory had reagents available for use when they had exceeded their expiration date. Survey findings follow: A) During a tour of the laboratory at 09:30 AM on 3/29/21 the following were observed available for use when they had exceeded their expiration date: In the laboratory room marked as number 3: * One of one bottle Sodium Hydroxide Solution Lot 184230, expiration date 8/2020, * One of one Reagent Bottle labeled 70% alcohol preparation date 9/23 /19, expiration date 10/23/19, * One of one reagent bottle labeled DI H2O preparation date 9/23/19, expiration date 10/23/19, * Nine of nine bottles of DNA Away lot 17180112 expiration date 2019-11 B) In an interview on 3/29/21 at 02:40 PM the laboratory staff member, identified as number three on the CMS 209 form, confirmed that the items identified above had exceeded their expiration date and were available for use.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i) (B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Through a review of new instrument validation documentation for the Luminex Molecular Diagnostic Analyzer, lack of documentation, as well as interviews with staff, it was determined the laboratory failed to have the director approve verification procedures to ensure they are adequate to determine the accuracy, precision, and other pertinent performance characteristics. Survey Findings follow: A. A review of the verification documentation for the Luminex Molecular Diagnostic Analyzer revealed the verification procedures were not approved and signed by the laboratory director.

	B. A review of the verification documentation for the Luminex Molecular Diagnostic Analyzer revealed the signature page of the procedure was signed on 03/18/2020 by laboratory personnel #3 (as listed on CMS form 209). C. Surveyor requested documentation of laboratory director approval for verification procedures performed on Luminex Molecular Diagnostic Analyzer. None was provided. D. In an interview on 03/29/2021 at 1330, Laboratory personnel #3 (as listed on CMS form 209) confirmed the verification procedures for the Luminex Molecular Diagnostic Analyzer were not approved or signed by the Laboratory Director.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Through interview with laboratory staff and review of personnel records it was determined that the laboratory failed to evaluate the competency of testing personnel twice during the first year the individual tests patient specimens. Findings follow: A) In an interview on 3/29/21 at 10:05 AM, the laboratory staff member identified as number three on the CMS 209 form stated that the laboratory opened and began testing patient specimens on 1/3/20 and that testing personnel, identified as numbers three and four on the CMS 209 form, were employed by the laboratory and tested patient specimens. B) Review of personnel documents revealed that testing personnel competency was evaluated on 6/22/20 and 3/4/21 for both of the testing personnel identified above. C) In an interview on 3/29/21 at 02:40 PM, the laboratory staff member, identified as number three on the CMS 209 form, confirmed that the laboratory began operation on 1/3/20 and that competencies for the two testing personnel identified above were not evaluated twice during the first year of employment.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: . Through review of personnel records, lack of documentation, and interview it was determined that the laboratory director did not specify in writing the examinations and procedures that two of two testing personnel are authorized to perform. Findings follow: A) Review of personnel records provided by the laboratory revealed that there was no written authorization to perform testing included for testing personnel identified as numbers three and four on the CMS 209 form. B) Upon request, the laboratory could not provide written authorization to test for the personnel identified

	above. C) In an interview on 3/29/21 at 09:45 AM., the technical supervisor identified as number three on the CMS 209 confirmed that written authorizations to test were not available for the testing personnel identified above and that he was unaware of the requirement of a written authorization to test.