

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1054857	(X3) Date Survey Completed 03/13/2023
Name of Provider or Supplier Alliance For Multispecialty Research, Llc	Street Address, City, State 1924 Alcoa Highway 4 And 5 Northwest, Knoxville, TN	
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	The laboratory was found not to be in compliance with the following CLIA conditions: D5016: 493.1210 Condition: Routine chemistry D6000: 493.1403 Condition: Laboratories performing moderate complexity testing, laboratory director
D5016	<p>ROUTINE CHEMISTRY CFR(s): 493.1210</p> <p>If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on observation, subsequent document review and phone interview after survey with the Quality Manager, review of patient test reports, request for laboratory records, review of procedure manual and Individualized Quality Control Plan (IQCP) and interview with the Quality Manager, the laboratory failed to meet the requirements for the chemistry specialty as evidenced by: 1. The laboratory failed to verify the accuracy of Methemoglobin (MetHb) in 2022 (Refer to D5217). 2. The laboratory failed to ensure the procedure and IQCP used for the Nova Stat Profile Prime Plus Chemistry analyzers were approved by the laboratory director (Refer to D5407). 3. The laboratory failed to follow the Individualized Quality Control Plan (IQCP) to perform and document external Quality Control (QC) every 30 days (Refer to D5445). 4. The laboratory failed to perform/document method comparisons for Nova Stat Profile Prime Plus Chemistry analyzers (Refer to D5775).</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or</p>

procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, subsequent document review and phone interview after survey with the Quality Manager, review of patient test reports, request for laboratory records, and interview with the Quality Manager, the laboratory failed to verify the accuracy of Methemoglobin (MetHb) assay in 2022 when patient testing began 09.23.2022. The findings include: 1. Observation of the laboratory on 03.13.2023 at approximately 9:15 a.m. revealed the Nova Stat Profile Prime Plus analyzer (serial # PP13220030C) in use for patient testing for MetHb. 2. Subsequent document review and phone interview on 03.20.2023 at approximately 2:45 p.m. with the Quality Manager revealed a second Nova Stat Profile Prime Plus analyzer (serial # PP1A210390C) in use for patient testing for MetHb. 3. Review of random patient test reports revealed MetHb was reported on the following patients/dates: Patient # 0043 reported on 09.23.2022 Patient # 0056 reported on 12.20.2022 4. Request made to the Quality Manager on 03.13.2023 at approximately 10:00 a.m. for records verifying the accuracy of the MetHb for 2022 revealed no records were available. 5. Interview with the Quality Manager on 03.13.2023 at approximately 10:30 a.m. confirmed the laboratory failed to verify the accuracy of MetHb test twice a year in 2022 with 12 individual patients tested for a total of 205 test panels that included MetHb reported since testing began on 09.23.2022.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, subsequent document review and phone interview after survey with the Quality Manager, review of patient test records, review of procedure manual and Individualized Quality Control Plan (IQCP) for the Nova Stat Profile Prime Plus Chemistry analyzer, and interview with the Quality Manager, the laboratory failed to ensure the procedure and IQCP used for the Nova Stat Profile Prime Plus Chemistry analyzer was approved by the laboratory director prior to patient testing that began on 09.23.2022. The findings include: 1. Observation of the laboratory on 03.13.2023 at approximately 9:15 a.m. revealed the Nova Stat Profile Prime Plus analyzer (serial # PP13220030C) in use for Partial Pressure of Carbon Dioxide (pCO₂), Partial Pressure of Oxygen (pO₂), and Methemoglobin (MetHb) patient testing. 2. Subsequent document review and phone interview on 03.20.2023 at approximately 2:45 p.m. with the Quality Manager revealed a second Nova Stat Profile Prime Plus analyzer (serial # PP1A210390C) in use for Partial Pressure of Carbon Dioxide (pCO₂), Partial Pressure of Oxygen (pO₂), and Methemoglobin (MetHb) patient testing. 3. Review of patient test records revealed pCO₂, pO₂, and MetHb were reported from the Nova Stat Profile Prime Plus analyzer on 09.23.2022 (Patient # 0043). 4. Review of the procedure manual for the Nova Stat Profile Prime Plus Analyzer revealed no approval of the procedure by the laboratory director. Procedure in use titled as "Blood Gases/Electrolytes/Metabolites in Whole Blood on the Stat Profile Prime Plus Analyzer" with an effective date 06.30.2022. 5. Review of the IQCP for the Nova Stat Profile Prime Plus Analyzer revealed no approval of the IQCP by the laboratory director. 6. Interview with the Quality Manager on 03.13.2023

at 10:30 a.m. confirmed the laboratory director had not approved the procedure and IQCP for the Nova Stat Profile Prime Plus Analyzer with patient testing that began on 09.23.2022.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of the Laboratory's Individualized Quality Control Plan (IQCP) for the Nova Stat Profile Prime Plus testing to include Partial Pressure of Carbon Dioxide (pCO₂), Partial Pressure of Oxygen (pO₂), and Methemoglobin (MetHb), request for every 30 day quality control (QC) documentation, and upon interview with the Quality Manager, it was determined the laboratory failed to perform and document external QC every 30 days as required since patient testing began on 09.23.2022. The findings include: 1. A review of the laboratory's IQCP states to perform external QC every 30 days for the Nova Stat Profile Prime Plus analyzer. 2. A request for the every 30 day QC documentation for all respective tests listed revealed no external QC documentation available for surveyor review since patient testing began on 09.23.2022. 3. An interview at approximately 10:30 a.m. on 03.13.2023 with the Quality Manager confirmed the external monthly QC failed to be performed /documented every 30 days since patient testing began on 09.23.2022.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, subsequent document review and phone interview after the survey with the Quality Manager, record review, and interview with the Quality Manager, the laboratory failed to compare results of Partial Pressure of Carbon Dioxide (pCO₂), Partial Pressure of Oxygen (pO₂), and Methemoglobin (MetHb) between their two Nova Stat Profile Prime Plus Chemistry analyzers in 2022 and 2023. The findings include: 1. Observation of the laboratory on 03.13.2023 at approximately 9:15 a.m. revealed the Nova Stat Profile Prime Plus Chemistry analyzer (serial # PP13220030C) in use for patient testing. 2. Subsequent document review and phone interview on 03.20.2023 at approximately 2:45 p.m. with the Quality Manager revealed a second Nova Stat Profile Prime Plus analyzer (serial # PP1A210390C) in

use for patient testing. 3. Review of laboratory records revealed no twice a year comparison between the instruments since patient testing began on 09.23.2022 through survey date of 03.13.2023. 4. Interview with the Quality Manager on 03.13.2023 at approximately 10:30 a.m. confirmed the laboratory failed to compare results between the Chemistry analyzers twice a year in 2022 and 2023.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
The laboratory director failed to review and approve validation studies (Refer to D6013), failed to ensure the laboratory was enrolled in proficiency testing in 2022 (Refer to D6015), failed participate in the training of five of five testing personnel prior to patient testing (Refer to D6029), failed to ensure an approved procedure manual was available for use (Refer to D6031), and failed to ensure job descriptions were present for the laboratory director, technical consultant, clinical consultant, and testing personnel (Refer to D6032).

D6013

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(ii)

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)(3) Ensure that-- (e)(3)(ii) 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 of the laboratory, subsequent document review and phone interview after the survey with the Quality Manager, review of validation studies, and interview with the Quality Manager, the laboratory director failed to review and approve validation studies for the Nova Stat Profile Prime Plus Chemistry analyzers prior to the start of patient testing on 09.23.2022. The findings include: 1. Observation of the laboratory on 03.13.2023 at approximately 9:15 a.m. revealed the Nova Stat Profile Prime Plus (serial #PP13220030C) moderately complex test system in use for patient testing. 2. Subsequent document review and phone interview on 03.20.2023 at approximately 2:45 p.m. with the Quality Manager revealed a second Nova Stat Profile Prime Plus (serial # PP1A210390C) moderately complex test system in use for patient testing. 3. Review of the validation studies for the Nova Stat Profile Prime Plus Chemistry analyzers revealed the validation studies had not been reviewed or approved by the laboratory director. 4. Interview with the Quality Manager on 03.13.2023 at approximately 10:30 a.m. and subsequent phone interview on 03.20.2023 at approximately 2:45 p.m. with the Quality Manager confirmed the

validation studies for two Nova Stat Profile Prime Plus Chemistry analyzers had not been reviewed or approved by the laboratory director. The laboratory began patient testing on 09.23.2022.

D6015

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)

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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, subsequent document review and interview after the survey with the Quality Manager, lack of documentation, and interview with the Quality Manager, the laboratory director failed to ensure the laboratory was enrolled in proficiency testing (PT) for the Partial Pressure of Carbon Dioxide (pCO₂) and Partial Pressure of Oxygen (pO₂) blood gas analytes in 2022 when patient testing began 09.23.2022. The findings include: 1. Observation of the laboratory on 03.13.2023 at 9:15 a.m. revealed a Nova State Profile Prime Plus Chemistry analyzer (serial # PP13220030C) in use for pCO₂ and pO₂ patient testing. 2. Subsequent document review and phone interview on 03.20.2023 at approximately 2:45 p.m. with the Quality Manager revealed a second Nova Stat Profile Prime Plus analyzer (serial # PP1A210390C) in use for pCO₂ and pO₂ patient testing. 3. Request for PT records from the Quality Manager on 03.13.2023 at approximately 9:30 a.m. revealed no proficiency testing records were available for 2022 when patient testing began 09.23.2022. 4. Interview with the Quality Manager on 03.13.2023 at approximately 10:30 a.m. confirmed the laboratory director failed to ensure the laboratory was enrolled in PT for the pCO₂ and pO₂ analytes in 2022.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), testing personnel training records, and interview with the Quality Manager, the lab director failed to participate in the training of five of five testing personnel for performance of Partial Pressure of Carbon Dioxide (pCO₂), Partial Pressure of Oxygen (pO₂), and Methemoglobin (MetHb) prior to patient testing that began on 09.23.2022. The findings include: 1. Review of

the Form CMS-209 revealed five testing persons who perform pCO₂, pO₂, and MetHb for patient testing. 2. Review of testing personnel training records revealed no evidence the lab director participated in the training process for pCO₂, pO₂, and MetHb testing for five of five testing personnel prior to patient testing that began on 09.23.2022. 3. Interview with the Quality Manager on 03.13.2023 at approximately 10:30 a.m. confirmed no evidence available to show the lab director participated in the training process for five of five testing personnel for performance of pCO₂, pO₂, and MetHb prior to patient testing that began on 09.23.2022.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, subsequent document review and phone interview after the survey with the Quality Manager, document request, review of patient test records and interview with the Quality Manager, the laboratory director failed to ensure an approved procedure manual was available for the use of the Nova Stat Profile Prime Plus Chemistry analyzers in 2022 and 2023 (Refer to D5401). The findings include: 1. Observation of the laboratory on 03.13.2023 at approximately 9:15 a.m. revealed the Nova Stat Profile Prime Plus analyzers (serial # PP13220030C) in use for Partial Pressure of Carbon Dioxide (pCO₂), Partial Pressure of Oxygen (pO₂), and Methemoglobin (MetHb) patient testing. 2. Subsequent document review and phone interview on 03.20.2023 at approximately 2:45 p.m. with the Quality Manager revealed a second Nova Stat Profile Prime Plus analyzer (serial # PP1A210390C) in use for Partial Pressure of Carbon Dioxide (pCO₂), Partial Pressure of Oxygen (pO₂), and Methemoglobin (MetHb) patient testing. 3. Request made to the Quality Manager on 03.13.2023 at 9:45 a.m. for an approved procedure manual for the use of the Nova Stat Profile Prime Plus Chemistry analyzers revealed the procedures had not been approved by the lab director (Refer to D5401). 4. Review of patient test records revealed patient testing for pCO₂, pO₂, and MetHb on the Nova Stat Profile Prime Plus analyzers began on 09.23.2022. 5. Interview with the Quality Manager on 03.13.2023 at approximately 10:30 a.m. confirmed the laboratory director failed to ensure an approved procedure manual was available for the use of the Nova Stat Profile Prime Plus analyzers from the time patient testing began on 09.23.2022 until the date of the survey on 03.13.2023.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and 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 results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory procedure manual and interview with the Quality Manager, the laboratory director failed to ensure job descriptions were present that outlined the duties and responsibilities of the laboratory director, technical consultant, clinical consultant, and testing personnel. The findings include: 1) Review of the laboratory procedure manual revealed no job descriptions were present for the laboratory director, technical consultant, clinical consultant, and testing personnel. 2) Interview with the Quality Manager on 03.13.2023 at 10:30 a.m. confirmed the laboratory director failed to ensure job descriptions were present for the laboratory director, technical consultant, clinical consultant and testing personnel.