Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0952240	11/11/2020
Name of Provider or Supplier	**Street Address, City, State**	
Yury J Nosaville, Md	8200 Wednesbury Suite 230, 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	The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D2016 - 42 C.F.R. 493.803 Condition: Successful participation in a proficiency testing program D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director 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. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent

	with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on a review of the laboratory's American Proficiency Institute proficiency testing records from 2020 and staff interview, it was revealed the laboratory failed to successfully participate in a proficiency testing program approved by HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory failed to successfully participate in the specialty of Immunohematology. Refer to D2162.
D2153	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(a) Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on a review of the laboratory's American Proficiency Institute proficiency testing records from 2020 and staff interview, it was revealed that the laboratory failed to attain a score of at least 100% for D (Rho) Type for API- first event 2020 and API- second event 2020 for D (Rho) Type, resulting in unsatisfactory analyte performance. Findings include: 1. API- first event 2020 the laboratory failed to participate, resulting in a score of 0% for D (Rho) Type. 2. API- second event 2020 the laboratory failed to participate, resulting in a score of 0% for D (Rho) Type. 3. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 11 /11/20) on 11/11/20 at 9:40 a.m. in the break room, after review of the records, confirmed the above findings.
D2154	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(b) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on a review of the laboratory's American Proficiency Institute proficiency testing records from 2020 and staff interview, it was revealed that the laboratory failed to attain an overall score of at least 100% for each testing event in the specialty of Immunohematology. Findings include: 1. API - first event 2020 the laboratory received the following unsatisfactory event score of 0% for Immunohematology. 2. API - second event 2020 laboratory received the following unsatisfactory event score of 0% for Immunohematology. 3. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 11/11/20) on 11/11/20 at 9:40 a.m. in the break room, after review of the records, confirmed the above findings.
D2155	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(c)

	Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a review of the laboratory's American Proficiency Institute proficiency testing records from 2020 and staff interview, it was revealed that the laboratory failed to participate in the API- first event 2020 and API- second event 2020 for D (Rho) Type, resulting in unsatisfactory performance. Findings include: 1. API- first event 2020 the laboratory failed to participate, resulting in a score of 0% for D (Rho) Type. 2. API- second event 2020 the laboratory failed to participate, resulting in a score of 0% for D (Rho) Type. 3. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 11/11/20) on 11/11/20 at 9:40 a. m. in the break room, after review of the records, confirmed the above findings.
D2162	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(f) Failure to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of the laboratory's American Proficiency Institute proficiency testing records from 2020 and staff interview, it was revealed the laboratory failed to achieve satisfactory performance (100% or greater) for the same analyte in two consecutive testing events or two out of three consecutive testing events in the specialty of Immunohematology for D (Rho) Type. Findings include: 1. API - first event 2020 the laboratory received a unsatisfactory score of 0% for D (Rho) Type. 2. API - second event 2020 the laboratory received a unsatisfactory score of 0% for D (Rho) Type. Two out of three unsatisfactory scores results in unsuccessful PT performance. 3. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 11/11/20) on 11/11/20 at 9:40 a.m. in the break room, after review of the records, confirmed the above findings.
D2163	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(g) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by:

	Based on a review of the laboratory's American Proficiency Institute proficiency testing records from 2020 and staff interview, it was revealed that the laboratory failed to attain satisfactory performance of 100% for each testing event in two consecutive testing events or two out of three consecutive testing events. Two out of three unsatisfactory scores results in unsuccessful PT performance in the specialty of Immunohematology. Findings include: 1. API - first event 2020 the laboratory received the following unsatisfactory event score of 0% for Immunohematology. 2. API - second event 2020 the laboratory received the following unsatisfactory event score of 0% for Immunohematology. 3. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 11/11/20) on 11 /11/20 at 9:40 a.m. in the break room, after review of the records, confirmed the above findings.
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: Based on a review of laboratory's American Proficiency Institute proficiency testing records from 2020, it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6018.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of the laboratory's American Proficiency Institute proficiency testing records from 2020, it was revealed the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in a HHS approved proficiency testing program. Refer to D2153, D2154, D2155, D2162, D2163.