Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D2181548	09/15/2020
Name of Provider or Supplier	**Street Address, City, State**	
Nelson Vein And Surgical Services	30915 Lorain Road, North Olmsted, OH	

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
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 record review and an interview with the Laboratory Director, the Laboratory Director failed to ensure that policies and procedures were approved, signed and dated before use. All patient Healgen COVID-19 IgG/IgM Rapid Test Cassette testing procedures performed in this laboratory from 06/25/2020 to 09/15/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure packet titled "Nelson Vein and Surgical Services, LLC", unapproved by the Laboratory Director and provided on the date of the inspection, did not find the Laboratory Director's approval via signature and date. 2. Further review of the laboratory's policy and procedure packet titled "Nelson Vein and Surgical Services, LLC", revealed the following statement under "Nelson Vein Laboratory Director Responsibilities": "Ensure that an approved procedure manual is available to all laboratory personnel" 3. The Laboratory Director confirmed the laboratory's established policy and procedure packet did not include the Laboratory Director's approval via signature and date. The interview occurred on 09/15/2020 at 9: 25 AM.
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: Based on record review and an interview with the Laboratory Director, the laboratory failed to define criteria consistent with the manufacturer's instructions and document room and refrigerator temperatures and humidity conditions for reliable Healgen COVID-19 IgG/IgM Rapid Test Cassette testing procedures. All Healgen COVID-19 IgG/IgM Rapid Test Cassette testing procedures performed in this laboratory from 06 /25/2020 to 09/15/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the "Healgen COVID-19 IgG/IgM Rapid Test Cassette Instruction for Use" documentation, provided on the date of the inspection, found the following statements: "The kit can be stored at room temperature or refrigerated (2-30C)." "This test should be performed at 15 to 30C." "Humidity and temperature can adversely affect results (especially with an RH over 80%)." 2. Review of the laboratory's policy and procedure packet titled "Nelson Vein and Surgical Services, LLC", unapproved by the Laboratory Director and provided on the date of the inspection, did not find any instructions to monitor and document room and refrigerator temperatures and humidity conditions, however revealed the following statements: "This test should be performed at 15-30C. Humidity and temperature can adversely affect results. Testing must be performed within one hour after opening the pouch. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air-conditioning" 3. The Inspector requested the laboratory's temperature and humidity documentation from 06/25/2020 to 09/15/2020 from the Laboratory Director. The Laboratory Director confirmed the laboratory did not establish a policy and procedure to monitor and document room and refrigerator temperatures and humidity conditions consistent with the manufacturer's instructions for Healgen COVID-19 IgG/IgM Rapid Test Cassette testing procedures, did not monitor and document room and refrigerator temperatures and humidity conditions from 06/25 /2020 to 09/15/2020 and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 09/15/2020 at 9:25 AM. C; degrees Celsius RH; Relative Humidity
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: Based on record review and an interview with the Laboratory Director, the laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for accuracy and precision. All patient Healgen COVID-19 IgG/IgM Rapid Test Cassette testing performed in this laboratory from 06 /25/2020 to 09/15/2020 had the potential to be affected by this deficient practice.

	Findings Include: 1. Review of the laboratory's policy and procedure packet titled "Nelson Vein and Surgical Services, LLC", unapproved by the Laboratory Director and provided on the date of the inspection, did not find any instructions for any performance specification activities for the Healgen COVID-19 IgG/IgM Rapid Test Cassette test system that was implemented on 06/25/2020. 2. The Inspector requested the laboratory's policy and procedure for performance specification activities and all performance specification documentation from the Laboratory Director. The Laboratory Director confirmed the laboratory did not establish a policy and procedure for performance specification activities for COVID-19 IgG/IgM testing procedures, did not conduct and document any performance specification activities and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 09/15/2020 at 10:25 AM.
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: Based on record review and an interview with the Laboratory Director, the laboratory failed to establish and demonstrate performance specifications for accuracy and precision of the modified specimen type, finger stick whole blood, prior to reporting patient Healgen COVID-19 IgG/IgM Rapid Test Cassette test results. All patient finger stick whole blood Healgen COVID-19 IgG/IgM Rapid Test Cassette testing performed in this laboratory from 06/25/2020 to 09/15/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the "Healgen COVID-19 IgG/IgM Rapid Test Cassette Instruction for Use" documentation, provided on the date of the inspection, found the following statement: "The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) test has not been evaluated with fingerstick specimens. Use of this test with fingerstick blood is not recommended." 2. Review of the laboratory's policy and procedure packet titled "Nelson Vein and Surgical Services, LLC", unapproved by the Laboratory Director and provided on the date of the inspection, did not find any instructions for any modified specimen type performance specification activities for the Healgen COVID-19 IgG/IgM Rapid Test Cassette test system that was implemented on 06/25/2020. 3. Further review of the laboratory's policy and procedure packet titled "Nelson Vein and Surgical Services, LLC", revealed instructions for whole blood finger stick sample collection for the Healgen COVID-19 IgG/IgM Rapid Test Cassette test procedures performed. 4. The Inspector requested the laboratory's policy and procedure for modified specimen type performance specification activities and all modified specimen type performance specification documentation from the Laboratory Director. The Laboratory Director confirmed the laboratory did not establish a policy and procedure for modified specimen type performance specification activities for

	COVID-19 IgG/IgM testing procedures, did not conduct and document any modified specimen type performance specification activities and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 09 /15/2020 at 10:25 AM.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the laboratory failed to perform and document negative and positive quality control (QC) testing procedures each day of qualitative patient Healgen COVID-19 IgG/IgM Rapid Test Cassette testing procedures performed. All patient Healgen COVID-19 IgG/IgM Rapid Test Cassette testing performed from 06/25/2020 to 09/15/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the "Healgen COVID-19 IgG/IgM Rapid Test Cassette Instruction for Use" documentation, provided on the date of the inspection, revealed the following statements: "Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance. Additional controls may be required according to guidelines or local, state, and/or federal regulations (such as 42 CFR 493.1256 or accrediting organizations." 2. Review of the laboratory's policy and procedure packet titled "Nelson Vein and Surgical Services, LLC", unapproved by the Laboratory Director and provided on the date of the inspection, did not find any instructions for negative and positive QC activities for the Healgen COVID-19 IgG/IgM Rapid Test Cassette test system that was implemented on 06/25/2020. 3. The Inspector requested the laboratory's policy and procedure for negative and positive QC activities and all QC documentation from the Laboratory Director. The Laboratory Director confirmed the laboratory did not establish a policy and procedure for negative and positive QC activities for the Healgen COVID-19 IgG/IgM Rapid Test Cassette testing procedures, did not conduct and document any negative and positive QC activities and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 09 /15/2020 at 10:25 AM.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the Laboratory Director failed to ensure that the quality control (QC) and quality assessment (QA) programs were established and maintained to identify failures in quality as they occur. Findings Include: 1. Review of the laboratory's policy and procedure packet titled "Nelson Vein and Surgical Services, LLC", unapproved by the Laboratory Director and provided on the date of the inspection, did not find any instructions for negative and positive QC and QA activities for the Healgen COVID-19 IgG/IgM Rapid Test Cassette test system that was implemented on 06/25/2020. 2. The Inspector requested the laboratory's policy and procedure for negative and positive QC and QA activities and all QC and QA documentation from the Laboratory Director. The Laboratory Director stated the test system has an internal procedural control, however confirmed the laboratory did not establish a policy and procedure for negative and positive QC and QA activities for the Healgen COVID-19 IgG/IgM Rapid Test Cassette testing procedures and did not conduct and document any negative and positive QC activities. The Laboratory Director provided two incomplete and unsigned "Data Collection Forms" (check lists), both dated 06/25/2020 and stated, however incomplete, they were the laboratory's QA documentation of which did not indicate any deficient items. Otherwise, the Laboratory Director was unable to provide any of the requested documentation on the date of the inspection. The interview occurred on 09/15/2020 at 10:25 AM.
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 record review and an interview with the Laboratory Director, the Laboratory Director failed to ensure that eight out of nine testing personnel (TP) were trained and had demonstrated that they could perform Healgen COVID-19 IgG/IgM Rapid Test Cassette testing procedures reliably to provide and report accurate results prior to performing patient testing. All patient Healgen COVID-19 IgG/IgM Rapid Test Cassette testing performed by TP#2, TP#3, TP#4, TP#5, TP#6, TP#7, TP#8 and TP#9 from 06/25/2020 to 09/15/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policies and procedures, unapproved by the Laboratory Director and provided on the date of the inspection, found the following instructions: "The skills required for performing each test method and for proper instrument use: Prior to performing their first test, the testing personnel would have read the package insert completely, and passed their test evaluation by the Lab Director." 2. Further review found a section titled "Competency Assessment Policy and Procedures" that revealed the following: "...testing personnel will be required to read the instructions for use manual The testing personnel will review the policies and procedures of the manual The testing personnel must verbally be able to report the steps of the testing protocol The testing personnel must perform test under

	the direct vision of the Laboratory Director in order to complete the competency assessment..." 3. Review of the "Healgen COVID-19 IgG/IgM Rapid Test Cassette Instruction for Use" documentation, provided on the date of the inspection, found the following statement: "Use of COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood /Serum/Plasma) is limited to laboratory personnel who have been trained." 4. The Inspector requested the laboratory's training and initial demonstration of competency documentation for TP#2, TP#3, TP#4, TP#5, TP#6, TP#7, TP#8 and TP#9 from the Laboratory Director. The Laboratory Director confirmed that the laboratory did not document training or initial demonstration of competency in order to reliably to provide and report accurate results prior to patient testing for TP#2, TP#3, TP#4, TP#5, TP#6, TP#7, TP#8 and TP#9 for the Healgen COVID-19 IgG/IgM Rapid Test Cassette testing procedures and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 09/15/2020 at 10:30 AM.