Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0244873	09/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Village Internal Medicine	1843 Quiet Cove, Fayetteville, NC	

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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of manufacturers' instructions and interview with staff (Nurse #1) 9 /23/21, the laboratory failed to follow manufacturer's instructions for the SARS-CoV-2 testing performed to ensure authorized Fact Sheets for patients and providers were included with SARS-CoV-2 test reports. The laboratory began using the CareStart COVID-19 Antigen Test on 5/6/21, and currently uses the Quidel QuickVue SARS Antigen Test for SARS-CoV-2. Manufacturer's instructions for the CareStart COVID-19 Antigen Test state on page 2 "Conditions of Authorization for Laboratory ... Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. ..." Manufacturer's instructions for the Quidel QuickVue SARS Antigen Test state on pages 7-8 "Conditions of Authorization for the Laboratory and Patient Care Settings...Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. ..." Interview with Nurse #1 at approximately 11:00 a.m. confirmed the laboratory does not provide the authorized Fact Sheets to patients and providers with the SARS-CoV-2 test result reports. She stated they were unaware that Fact Sheets should be provided to patients and providers.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems

	activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of 2019, 2020, and 2021 hematology quality control (QC) records and testing personnel (TP #1) interview 9/23/21, the laboratory failed to retain hematology QC assay sheets for at least two years. Findings: Review of hematology QC records revealed the following EIGHTCHECK-3WP X-TRA QC assay sheets were not retained for at least two years: a. Lot #00840710, 00840711, 00840712 - expiration 7/1/20 b. Lot #03360710, 03360711. 03360712 - expiration 3/10/21 Exit interview with TP #1 at approximately 2:30 p.m. confirmed the laboratory failed to retain the QC assay sheets.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2019, 2020, and 2021 API (American Proficiency Institute) proficiency testing records, and interview with testing personnel (TP #1) 9/23/21, the laboratory failed to document review and evaluation of all proficiency testing results received for 3 of 18 proficiency testing events. Findings: The laboratory's "PROFICIENCY TESTING PROCEDURE" states "... TEST GRADES: Test grades are provided by API. Printout results and provide to the Laboratory Director to review and sign. Follow the corrective action checklist provided by the manufacturer for any unacceptable grades needing action. ..." An untitled page in the procedure manual states " Review results for unacceptable results. ... Document corrective action taken for all unacceptable results or failures. ... Review report for ungraded results. Any analyte that is not graded for some reason (e.g. lack of consensus) should be compared with the information provided in the Data Summary report. The reviewer should do a self-grading of those results and document their findings. Take appropriate corrective action if required. ..." Review of 2019, 2020, and 2021 API proficiency testing records revealed: a. On the 2020 1st chemistry core event, the laboratory failed to evaluate the ungraded ALT (alanine aminotransferase) result for sample CH-01. b. On the 2020 1st hematology event, the laboratory failed to evaluate the 80% scores for hematocrit, MCH (mean corpuscular hemoglobin), MCHC (mean corpuscular hemoglobin concentration), MCV (mean corpuscular volume), and RDW (red cell distribution width). In addition, the results were not signed by the laboratory director to indicate review. c. On the 2021 1st chemistry core event, the laboratory failed to evaluate the 60% score for Vitamin D. During interview at approximately 12:30 p.m., TP #1 confirmed that the evaluations were not documented.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic

	examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and interview with testing personnel (TP #1) 9/23/21, the laboratory's procedure manual was not complete and current for the testing performed. Review of the laboratory's procedure manual revealed the laboratory did not have a written procedure for reporting patient positive and negative SARS-CoV-2 test results to the appropriate public health authorities. During interview at approximately 11:40 a.m., TP #1 confirmed that the laboratory did not have a written procedure for reporting both positive and negative patient COVID test results.
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 review of manufacturer's instructions and review of 2019, 2020, and 2021 temperature logs 9/23/21, the laboratory failed to define an acceptable range for refrigerator temperature that was consistent with manufacturer's instructions for storage of the hematology control material. The manufacturer's product insert for the EIGHTCHECK-3WP X-TRA hematology quality control material states "STORAGE AND STABILITY ... 2. Store EIGHTCHECK-3WP X-TRA vials at 2-8 degrees C. ..." Review of the laboratory's 2019, 2020, and 2021 temperature logs revealed the acceptable range for refrigerator temperature was listed as 2-10 degrees Celsius. The laboratory's acceptable range was not consistent with the acceptable range of 2-8 degrees Celsius specified by the manufacturer.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory

	must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of 2019 and 2020 hematology maintenance logs and QC records for the Sysmex XP-300 hematology analyzer 9/23/21, the laboratory failed to document daily maintenance of the Sysmex XP-300 analyzer 4 of 14 days in December of 2019 and 8 of 21 days in November of 2020. Findings: Review of maintenance log for the Sysmex XP-300 analyzer revealed the following daily maintenance "Perform Shutdown, Verify Background, Verify Vacuum/Pressure, Check Trap Chamber, Perform Quality Control." Review of December 2019 maintenance log revealed daily maintenance was not documented on 12/6/19, 12/17/19, 12/19/19 and 12/20/19. Review of December 2019 QC records revealed QC was performed on the days in which maintenance was not documented. There was no documentation to indicate patient testing was not performed. Review of November 2020 maintenance log revealed daily maintenance was not documented on 11/16/20, 11/17/20, 11/18/20, 11 /19/20, 11/20/20, 11/23/20, 11/24/20, and 11/25/20. Review of November 2020 QC records revealed QC was performed on the days in which maintenance was not documented. There was no documentation to indicate patient testing was not performed.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of 2019 hematology quality control (QC) records, QC package inserts and maintenance logs for the Sysmex XP-300 hematology analyzer 9/23/21, the laboratory failed to document QC for the Sysmex XP-300 analyzer 2 of 21 days in September of 2019 and 5 of 23 days in October of 2019. Findings: Review of 2019 hematology QC records for daily runs revealed a gap in QC documentation from 9/26 /19, when QC Lot #91970710 was in use, until 10/9/19 when QC Lot #92810710 was put into use. Review of September 2019 hematology QC records for daily runs revealed no documentation of QC results for 9/27/19 and 9/30/19. Review of October 2019 hematology QC records for daily runs revealed no documentation of QC results for 10/1/19. 10/2/19, 10/3/19, 10/4/19 and 10/8/19. Review of maintenance logs for the Sysmex XP-300 revealed a check mark for "Perform Quality Control" on 9/27/19, 9/30/19, 10/1/19, 10/2/19, 10/3/19, 10/4/19 and 10/8/19.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2019, 2020, and 2021 laboratory records, and interview with testing personnel (TP #1) 9/23/21, the laboratory director failed to ensure the establishment and maintenance of an effective quality assessment program designed to identify and correct problems and prevent their recurrence. Findings: Review of the "Quality Assurance Program" policy revealed a list of activities conducted on a routine basis by the laboratory. Examples: a. "Pre-analytic: 1. Monthly temperature and humidity records are reviewed." b. "Analytic: 1. Quality control records (Levy-Jennings) are reviewed monthly. 2. Maintenance records for analyzers are reviewed monthly. ..." c. "Post -Analytic: 1. Review of the Proficiency testing results by Laboratory director. 2. LIS validation reviewed every six months. ..." The laboratory's quality assessment program failed to identify the following issues identified during the survey: 1. The laboratory failed to establish an acceptable refrigerator temperature range consistent with the range specified by the manufacturer for storage of the hematology quality control material (see D5413). 2. The laboratory failed to retain quality control assay sheets for the EIGHTCHECK-3WP X-TRA hematology control material as required (see D3031) and failed to perform and document hematology quality control as required each day of patient testing (see D5481). 3. The laboratory failed to document maintenance as specified by the manufacturer for the Sysmex XP-300 hematology analyzer (see D5429). 4. The laboratory failed to ensure evaluation of all unacceptable and ungraded proficiency testing results (see D5211). 5. The laboratory failed to perform LIS (laboratory information system) validation activities every six months. The laboratory completed an LIS validation for test result calculations on 4/2/18 and an LIS validation for low and high alerts on the hematology analyzer on 4/1/21. The laboratory failed to perform LIS validation activities every six months as required by their policy from 4/2/18 until 4/1/21, a period of approximately 2 years. Exit interview with TP #1 at approximately 2:30 p.m. confirmed the laboratory failed to perform LIS validation activities every six months as established in the "Quality Assurance Program".