Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0244873	08/02/2018
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of 2017 and 2018 American Proficiency Institute (API) proficiency testing (PT) records, and testing personnel (TP) interview 08/02/18, the laboratory director and/or testing personnel failed to sign attestation statements for laboratory PT testing performed. Review of 2017 and 2018 API PT records the laboratory director and/or testing personnel failed to sign attestation statements for the following API PT events in which the laboratory participated. 1. API 2017 Chemistry Miscellaneous 2nd Event, laboratory director failed to sign attestation statement. 2. API 2018 Chemistry Core 2nd Event, laboratory director and testing personnel failed to sign attestation statement. 3. API 2018 Hematology/Coagulation 1st Event, laboratory director and testing personnel failed to sign attestation statement. 4. API 2018 Hematology /Coagulation 2nd Event, laboratory director and testing personnel failed to sign attestation statement. Interview with TP #1 at approximately 12:20 p.m. confirmed testing personnel and/or laboratory director failed to sign attestation statements for all API testing events in which the laboratory participated.
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 laboratory procedure manual, review of patient test reports and testing personnel (TP) interview 08/02/18, the laboratory failed to ensure the procedure manual was complete and current for the testing performed. The laboratory performs hematology testing on Sysmex XP-300 hematology analyzer, and chemistry testing on the Beckman Coulter Access 2 and the Ace Axcel chemistry analyzers. 1. Review of laboratory procedure manual revealed procedure "Laboratory Quality Control Policy", the quality control policy failed to include laboratory specific information such as; what quality control material is used for each test system and/or analyte, the frequency for performance of quality control for each test system and/or analyte, the criteria used to determine if quality control results are acceptable for each test system and/or analyte and the corrective actions to take if quality control results are unacceptable. For example; the policy states, "2. For clinical methods, the laboratory must choose QC material that, if available, is of a similar matrix to that of patient specimens and the QC material must be treated in the same manner as patient specimens and go through all analytic phases.....4. If the manufacturer does not specify a frequency for performing QC, the laboratory must determine the interval in which the measuring system is expected to be stable. CLIA requires that QC be tested, at minimum, every 24 hours that testing occurs.....13. Each laboratory must specify in writing the type of QC to be tested for each procedure, the frequency of testing, the QC acceptance criteria for each test and the actions to take if the QC results are unacceptable. These criteria may be included in the test procedure or in a separate document. " Interview with TP #1 at approximately 11:00 a.m. confirmed the "Laboratory Quality Control Policy" failed to include laboratory specific information such as; what quality control material is used for each test system and/or analyte, the frequency for performance of quality control for each test system and/or analyte, the criteria used to determine if quality control results are acceptable for each test system and/or analyte and the corrective actions to take if quality control results are unacceptable. 2. Review of random patient test reports and laboratory procedure manual revealed no documentation of reference intervals (normal values) established for the laboratory testing performed. Review of random patient test reports, #103170, #23050 and #30360 revealed reference intervals (normal values) are recorded on patient test reports. Review of laboratory procedure manual revealed no documentation of the reference intervals (normal values) established for the laboratory testing performed. Interview with TP #1 at approximately 11:00 a.m. confirmed the laboratory's procedure manual does not include documentation of the reference intervals (normal values) established by the laboratory. She stated they adapted their normal values from Lab Corp. 3. Review of laboratory procedure manual revealed no

	policy or procedure for panic or alert values established by the laboratory for the laboratory testing performed or the protocol for reporting panic or alert values. Interview with TP #1 at approximately 11:00 a.m. confirmed the laboratory procedure manual does not include a policy or procedure for panic or alert values established by the laboratory and it does not include the protocol for reporting panic or alert values for the laboratory testing performed. 4. Review of laboratory procedure manual revealed no policy or procedure for entering test results in the patient record. Interview with TP #1 at approximately 11:00 a.m. confirmed the laboratory procedure manual does not include a procedure for entering test results in the patient record. She stated they were working on it. 5. Review of laboratory policy and procedure manual revealed no policy or procedure for the course of action to take if a test system becomes inoperable. Interview with TP #1 at approximately 11:00 a.m. confirmed the laboratory procedure manual does not include a procedure for the course of action to take if a test system becomes inoperable.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of patient test report and testing personnel (TP) interview 08/02/18, the laboratory director failed to ensure the laboratory's Prostate-Specific Antigen (PSA) test reports included the identity of the assay method used. The laboratory performs PSA testing using the Beckman Coulter Access chemistry analyzer. Review of manufacturer's instructions for the "Access Hybritech PSA Prostate-Specific Antigen" state "WARNING...The concentration of PSA in a given specimen determined with assays from different manufacturers can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the PSA assay used...." Review of random patient test report, Patient # 67510, revealed the test report failed to include the identity of the assay method used for the PSA testing. Interview with TP #1 at approximately 12:20 p.m. confirmed the laboratory's test reports for PSA testing failed to include the identity of the assay method used.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual, review of laboratory records, review of testing personnel records and testing personnel (TP) interview 08/02/18, the technical consultant (laboratory director) failed to evaluate and assure the competency

	of 3 of 3 testing personnel. Review of laboratory procedure manual revealed policy "Competency Assessment Policy", signed by laboratory director on 8/1/18. The policy states "....2. Competency must be assessed a minimum of twice in the first year of employment for testing personnel and annually thereafter...6. Competency assessment, which includes the six procedures above, must be performed on testing personnel for each test that the individual is approved to perform." Review of laboratory records revealed the laboratory began patient testing on the Sysmex XP-300 hematology analyzer 7/17, the Beckman Coulter Access 2 chemistry analyzer 9 /17 and the Ace Axcel chemistry analyzer 1/18. Review of testing personnel competency records revealed no competency assessments were performed since patient testing began for 3 of 3 testing personnel. Interview with TP #1 at approximately 10:30 a.m. confirmed the technical consultant (laboratory director) had not performed competency assessments for 3 of 3 testing personnel. She stated, everyone has been trained, and she was the only one performing chemistry testing, the other testing personnel perform hematology only. But they have not had time to access competency.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on laboratory record review, review of laboratory policy and procedure manual and testing personnel (TP) interview 08/02/18, the laboratory director failed to ensure that a quality assessment program was established and maintained. Review of laboratory records revealed the laboratory director is reviewing quality control and maintenance records periodically. Review of laboratory policy and procedure manual revealed no documentation that the laboratory director had established or maintained a quality assessment program for the laboratory. Interview with TP #1 at approximately 12:20 p.m. confirmed the laboratory director had not established or maintained a quality assessment program for the laboratory. She stated they were in the process of establishing their quality assessment program.