Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0708389	04/02/2018
Name of Provider or Supplier	**Street Address, City, State**	
West Front Primary Care	4290 Cooper Ridge Drive, Traverse City, MI	

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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to test the microbiology (bacteriology) and hematology (mycology, parasitology, urine microscopic analysis and semen analysis) proficiency testing samples the same number of times that it routinely tests patient samples for five (2nd and 3rd events in 2016 and 1st-3rd events in 2017) of five events reviewed. Findings include: 1. On April 2, 2018 at 11:56 a.m., record review of the American Proficiency Institute (API) revealed for five of five events in 2016 and 2017 the laboratory had multiple testing reports for each analyte in the microbiology and hematology sections as follows: a. hematology 2nd event 2016 - all testing completed by ten personnel b. microbiology 2nd event 2016 - all testing completed by five personnel c. microbiology 3rd event 2016 - all testing completed by seven personnel d. hematology 1st event 2017 - all testing completed by ten personnel e. microbiology 1st event 2017 - all testing completed by seven personnel f. hematology 2nd event 2017 - all testing completed by ten personnel g. microbiology 2nd event 2017 - all testing completed by nine personnel h. hematology 3rd event 2017 - all testing completed by eleven personnel i. microbiology 3rd event 2017 - all testing completed by ten personnel 2. During the interview on April 2, 2018 at 11:56 a.m., the office manager confirmed the proficiency testing samples were not tested like patient samples. ***Repeat Deficiency from December 13, 2011 survey***
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination,

	and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to maintain the original American Proficiency Institute (API) proficiency testing program report forms, worksheet log, and/or the signed attestation statement sheet for five (2nd and 3rd events in 2016 and 1st-3rd events in 2017) of five events reviewed. Findings include: 1. On April 2, 2018 at 11:56 a.m., record review of the final graded API proficiency testing reports revealed the laboratory failed to maintain the original proficiency testing program report forms, worksheet logs, and the signed attestation statement sheets for five of five events in 2016 and 2017 as follows: a. microbiology original paperwork - 2nd event in 2016 and 1st and 2nd events in 2017 b. hematology original paperwork - 2nd and 3rd events in 2016 and 1st event in 2017 c. microbiology worksheet logs - 2nd event 2016 d. hematology signed attestation statement sheets - 3rd event in 2016 and 2017 2. During the interview on April 2, 2018 at 11:56 a.m., the office manager confirmed the laboratory failed to maintain all the proficiency testing program report form, microbiology worksheet logs, and the signed attestation statement sheets. .
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to ensure written competency policies were established, contained the requirements from subpart M, and implemented for 15 (#1 - #15) of 15 testing personnel performing the bacteriology, mycology, parasitology, urine microscopic analysis, and the hematology semen analysis in 2016 and 2017. Findings include: 1. On April 2, 2018 at 10:46 a.m., record review revealed the laboratory did not establish a written competency policy that included the six requirements from subpart M for the bacteriology, mycology, parasitology, urine microscopic analysis, and the hematology semen analysis that included the following: a. Direct observations of routine patient test performance, patient preparation, specimen handling, processing, and testing. b. Monitoring the recording and reporting of patient test results. c. Review of test results, worksheets, quality control records, proficiency testing results, and preventive maintenance. d. Direct observation of performance of instrument maintenance and function checks. e. Assessment of test performance through testing previously analyzed samples. f. Assessment of problem solving skills. 2. On April 2, 2018 at 10:46 a.m., record review revealed the laboratory did not have any documentation to show that for 15 of

	15 testing personnel the competency assessments were performed and documented for the bacteriology, mycology, parasitology, urine microscopic analysis, and the hematology semen analysis testing in 2016 and 2017. 3. On April 2, 2018 at 10:46 a. m. when queried, the office manager was not able to provide the surveyor with a competency policy that contained the six minimal requirements and the documentation of those requirements for 15 of 15 testing personnel in 2016 and 2017. 4. During the interview on April 2, 2018 at 10:46 a.m., the office personnel confirmed the laboratory did not establish a competency policy that contained the requirements from Subpart M and did not implement the policy in 2016 and 2017. ***Repeat Deficiency from December 13, 2011 Survey***
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: The laboratory failed to meet applicable analytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to establish and follow written procedures for the microbiology and hematology testing. Refer to D5401. 2. The laboratory failed to follow the manufacturer's operator's manual to monitor and record room temperatures and humidity. Refer to D5411. 3. The laboratory failed to monitor and document the incubator temperature. Refer to D5413. 4. The laboratory failed to label the potassium hydroxide (KOH) reagent with the preparation and expiration date . Refer to D5415. 5. The laboratory failed to perform and document the two times per year maintenance on the stat spin centrifuges. Refer to D5429. 6. The laboratory failed to check each batch, lot number, and shipment of Bacitracin discs for positive and negative reactivity . Refer to D5471. 7. The laboratory failed to perform and document media checks with each new batch, lot, or shipment for sterility, the ability to support growth, and selectivity/inhibition of growth. Refer to D5477. 8. The laboratory failed to document corrective action taken for improper incubator temperatures. Refer to D5785. The cumulative effect of the failure of the laboratory to meet the requirements of 493.1251 through 493.1289 constitutes condition-level noncompliance.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: . Based on procedure manual review and interview, the laboratory failed to establish and follow written procedures for the microbiology and hematology testing for two

	(2016 and 2017) of two years. Findings include: 1. On April 2, 2018 at 1:14 p.m., procedure manual review revealed the laboratory did not establish and implement procedures for the routine microbiology and hematology testing as follows: a. Potassium hydroxide (KOH) b. microscopic urinalysis c. strep culture preparation, collection, processing, testing and resulting d. wet mount e. semen analysis patient preparation, collection, processing, testing, and resulting f. temperature (refrigerator, room temperature, humidity, and incubator) monitoring, recording, and corrective action g. reagent preparation, expiration, storage, and use h. retention of medical records, patient records, laboratory testing in the electronic medical record system 2. During the interview on April 2, 2018 at 1:14 p.m., the office manager confirmed the above procedures were not available to the surveyor on the day of the survey. ***Repeat Deficiency from December 13, 2011 survey***
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: . Based on operator's manual review and interview, the laboratory failed to follow the manufacturer's operator's manual to monitor and record the room temperature and humidity readings in the laboratory for 23 (April 2016 to March 2018) of 23 months reviewed to ensure proper microscope operation in suites A and E. Findings include: 1. On April 2, 2018 at 1:24 p.m., procedure review of "Environment of using and placing" for the Seiler microscope revealed the laboratory was to monitor and document the room temperature and humidity. 2. On April 2, 2018 at 1:24 p.m. when queried, the office manager was unable to provide the surveyor with documentation to show the room temperature and the humidity readings were being monitored and documented for 23 of 23 months. 2. During the interview on April 2, 2018 at 1:24 p. m., the office manager confirmed the room temperature and humidity readings were not monitored and documented.
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 interview, the laboratory failed to monitor and document the incubator temperature for 1) three days of 52 weeks reviewed in 2016 and for 2) seven days of 52 weeks reviewed in 2017 to ensure optimal bacterial growth. Findings include: 1. On April 2, 2018 at 2:10 p.m., record review of the "Cultures" log sheets

	revealed 1) for three days (April 7, 25, and 28) of 52 weeks reviewed in 2016 and for 2) seven days (February 10 and 27, March 10, August 2, 15, 23, and 29) of 52 weeks reviewed in 2017 the laboratory failed to monitor and document the incubator temperature. 2. On April 2, 2018 at 2:10 p.m. when queried, the office manager was not able to provide documentation for the missed incubator temperatures. 3. During the interview on April 2, 2018 at 2:10 p.m., the office manager confirmed the incubator temperatures were not monitored and documented.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: . Based on observation and interview, the laboratory failed to label the potassium hydroxide (KOH) reagent with the preparation and expiration date for the current bottles in use. Findings include: 1. On April 2, 2018 at 10:45 a.m. during a tour of laboratory suites A, B, and E, the surveyor observed the mycology KOH reagents in use. There was no documentation on the reagent bottles for the preparation and expiration dates. 2. During the interview on April 2, 2018 at 10:45 a.m., the office manager confirmed the KOH bottles were not labeled with the preparation or expiration dates.
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 procedure review, record review, and interview, the laboratory failed to perform and document the two times per year maintenance on the stat spin centrifuges in suite A, B, and E for one (2017) of three years reviewed. Findings include: 1. On April 2, 2018 at 1:10 p.m., procedure review of the "CLIA Policy for Equipment" revealed the laboratory is to perform "two times per year" the revolutions per minute and the timing on the stat spin centrifuges. 2. On April 2, 2018 at 1:10 p.m., record review for the maintenance on the stat spin centrifuges revealed the laboratory did not have any documentation for one (2017) of three years reviewed. 3. During the interview on April 2, 2018 at 1:10 p.m., the office manager confirmed the stat spin centrifuge maintenance was not performed and documented in 2017.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and

	shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on document review and interview, the laboratory failed to check each batch, lot number, and shipment of Bacitracin discs for positive and negative reactivity for 15 (November 17, 2016 to March 2018) of 16 months reviewed. Findings include: 1. On April 2, 2018 at 2:30 p.m., document review of the "Bacitracin Disc Quality Control (Weekly)" log sheet revealed the laboratory did not check each batch, lot number, and shipment for positive and negative reactivity for 15 of 16 months reviewed. 2. On April 2, 2017 at 2:30 p.m. when queried, the office manager was unable to provide the surveyor the documentation. 3. During the interview on April 2, 2018 at 2:30 p.m., the office manager confirmed the laboratory failed to check each batch, lot number, and shipment of Bacitracin discs for positive and negative reactivity.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to perform and document media checks for the "BBL Selective Strep" agar plates with each new batch, lot, or shipment for sterility, the ability to support growth, and selectivity /inhibition of growth for 23 (April 2017 to March 2018) of 23 months reviewed. Findings include: 1. On April 2, 2018 at 3:30 p.m., record review of the physical condition for the "BBL Selective Strep" agar plates revealed there was no documentation to show sterility, the ability to support growth, selectivity/inhibition of growth for 23 of 23 months reviewed with each new batch, lot or shipment. 2. During the interview on April 2, 2018 at 3:30 p.m., the office manager confirmed the media checks were not performed and documented with each new batch, lot or shipment.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by:

	. Based on document review and interview, the laboratory failed to document corrective action taken for improper incubator temperatures for 1) 20 days of 52 weeks reviewed in 2016 and 2) six days of 52 weeks reviewed in 2017 for optimal bacterial growth. Findings include: 1. On April 2, 2018 at 2:10 p.m., document review of the "Culture" log sheets revealed there was no corrective action taken for the incubator temperatures recorded above the stated range of 35-37 degrees F for 1) 20 days of 52 weeks reviewed in 2016 and 2) for six days of 52 weeks reviewed in 2017 as follows: a. July 2016 - 8, 9, 11, 27, 28, and 29 b. August 2016 - 16, 22, 24, 26, 28, 30, and 31 c. September 2016 - 19, 21, 22, 26, 27, 28, and 30 d. February 2017 - 15 and 23 e. April 2017 - 22 and 24 f. June 2017 - 13 and 23 2. During the interview on April 2, 2018 at 2:10 p.m., the office manager confirmed no corrective action was documented for the out of range temperatures.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to establish a system to ensure the manually entered patient final test results were entered into the patient's electronic medical record (EMR) for two (#5 and #8) of 18 patient charts audited. Findings include: 1. On April 2, 2018 at 3:00 p.m., record review for two of 18 patient charts audited revealed the final patient test result for the potassium hydroxide (KOH) was not included in the patient's EMR. 2. On April 2, 2018 at 3:00 p.m. when queried, the office manager was unable to provide the surveyor the final patient test result in the patient's EMR. 3. During the interview on April 2, 2018 at 3:00 p.m., the office manager confirmed the final KOH test result was not routinely monitored to verify final results in a patient's EMR.
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 record review and interview, the laboratory failed to ensure the American Proficiency Institute (API) final graded microbiology (bacteriology) and hematology

	(mycology, parasitology, urine microscopic analysis, and the hematology semen analysis) were reviewed by the appropriate testing staff for five (2nd and 3rd events in 2016 and 1st-3rd events in 2017) of five events reviewed. Findings include: 1. On April 2, 2018 ay 11:56 a.m., record review revealed for five of five testing events the final graded API proficiency testing reports were not reviewed by the laboratory director and the testing personnel as follows: a. laboratory director - no review on the hematology 3rd event in 2016 and 2017 b. testing personnel - no review of the microbiology and hematology for testing events 2nd and 3rd in 2016 and 1st-3rd in 2017. 2. During the interview on April 2, 2018 at 11:56 a.m., the office manager confirmed the laboratory director and the testing personnel did not review the final graded proficiency testing reports.