Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2182399	09/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Westchester Putnam Gastroenterology	2424 Route 6, Brewster, NY	

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 the McKesson Consultant Diagnostics Rapid Strep A (RST); Quidel Quick Vue Influenza A & B; T & D Diagnostics Sienna Covid- 19 Antigen; and Deland Urine Human Chorionic Gonadotropin (uHcg) manufacturer's package inserts; lack of Quality Control (QC) records, as well as interview with the general supervisor (GS), the laboratory failed to follow the test kit QC requirements from July 1, 2021, though the survey date. FINDINGS: 1. The McKesson Consultant Diagnostics Rapid Strep A (RST); Quidel Quick Vue Influenza A & B; and T & D Diagnostic Sienna Covid- 19 Antigen manufacturer's requirements included instructions for QC materials contained within the test kits be utilized for each new lot and/or shipment. It was noted that the Dealand Urine Pregnancy manufacturer's requirements did not require performance of an external control prior to patient testing. a. No documentation of test kit lot numbers and expiration dates were available as the laboratory did not perform such activity. It was not possible to determine test kit volume received and utilized from the July 1, 2021, through the survey date. It was also not possible to determine patient volume affected as tests were performed and results documented by the Clinical Medical Assistant (CMA) personnel in the Electronic Medical Record (EMR) from July 1, 2021, through the survey date. 2. The general supervisor (GS) confirmed on September 13, 2023, at approximately 10:30 A.M. that providers ordered tests in the EMR and CMA personnel performed and documented the results. The GS also confirmed lack of test kit lot number and expiration date documentation as well as lack of QC records.

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 lack of competency records and an interview with GS, the laboratory director (LD) failed to develop and maintain a competency evaluation policy for the GS based on the duties and responsibilities. FINDINGS: 1. The GS confirmed on September 13, 2023, at 10:30 A.M. that the LD failed to develop and maintain a GS competency evaluation policy. Refer to D6029.
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 the instructions included in the waived test manufacturer's package insert, lack of phlebotomy/waived testing room temperature and humidity records; and an interview with the GS, the laboratory failed to monitor and document temperatures and humidity of the room where waived laboratory test kits were stored and laboratory testing was performed from July 1, 2021, through the survey date. FINDINGS: 1. The McKesson Consultant Diagnostics Rapid Strep A (RST); Quidel QuickVue Influenza A & B; T & D Diagnostic Sienna Covid- 19 Antigen; and Dealand uHcg manufacturer's package insert included instructions for test kit storage temperature ranges of 15 - 30 C or 68 - 86 F and humidity range of 10 - 80%. a. No documentation of room temperature and humidity were available as the laboratory did not perform such activity. 2. The GS confirmed on September 13, 2023, at approximately 11:30 A.M. that the laboratory failed to install a thermometer as well as monitor and document the temperatures and humidity of the room where waived test kits were stored and laboratory testing was performed.
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 a review of the ABX Horiba Micros 6 and Beckman Coulter Pentra 400 validation records; TOSOH AIA 900 patient testing log sheets; QC records; and an interview with the GS, the laboratory failed to perform and document complete validation studies to verify the hematology, chemistry, and endocrinology analyzer performance specifications. FINDINGS: 1. The GS confirmed on September 13, 2023, at approximately 11:00 A.M. that the laboratory failed to perform and document complete validation studies to verify ABX Horiba Micros 60 hematology analyzer, Beckman Coulter Pentra 400 chemistry analyzer, and TOSOH AIA 900 endocrinology analyzer performance specifications prior to patient testing. 2. The laboratory installed the hematology, chemistry, and endocrinology analyzers on November 17, 2021. It was noted that the laboratory successfully performed precision, linearity, calibration, and training but failed to perform correlation methods for accuracy. 3. The laboratory temporarily ceased moderate complexity testing January 2022 and resumed testing July 1, 2023, through the survey date. a. It was noted that the laboratory performed and documented the required analyzer control and calibrations from July 1, 2023, through the survey date. 4. Approximately four hundred patient samples were tested and reported from July 1, 2023, through the survey date.
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 review of the laboratory's standard Operation Procedure (SOP) manual; review of QC, calibration, validation, and personnel records; as well as confirmed by interview with GS, the LD failed to provide overall management for all phases of moderate complexity testing. FINDINGS: The LD failed to ensure that: 1. Complete validation studies were performed to verify hematology, chemistry, and endocrinology analyzer performance specifications. Refer to 6013. 2. CMA personnel performing waived laboratory testing were complying with test kit manufacturer's requirements for QC, storage temperature, as well as the reporting of accurate results. Refer to D6014. 3. Development and maintenance of a GS competency evaluation policy. Refer to D6029.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

	This STANDARD is not met as evidenced by: Based on review of the ABX Horiba Micros 60 and Beckman Coulter Pentra 400 validation records; TOSOH AIA 900 patient testing log sheets; QC records; and an interview with the GS, the LD failed to perform and document complete validation studies to verify the hematology, chemistry, and endocrinology analyzer performance specifications prior to patient testing from July 1, 2023, through the survey date. Refer to D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of the laboratory's SOP manual, personnel records, and an interview with the GS, the LD failed to ensure that the CMA personnel were complying with test kit manufacturer's requirements for QC, storage temperature, as well as the reporting of accurate results. Refer to D1001 and D5413.
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 the lack of competency records and interview with GS, the LD failed to develop and maintain a competency evaluation policy for the GS based on the duties and responsibilities. Refer to D5209.