Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2237459	03/07/2023
Name of Provider or Supplier	**Street Address, City, State**	
Bethpage Medical, Pllc	244 Crossways Park W, Woodbury, 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
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on review of the TOSOH G6 procedure manual and direct observation of the analyzer on 3/7/23 at 1:30 P.M., the laboratory failed to follow the manufacturer's requirement which states, "that an anti-static mat must be placed in front of the analyzer for a 20-80% humidity".
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 API PT reports, the laboratory did not evaluate and document corrective action for the PT scores less than 100% for the following analytes. Findings: 1. General Chemistry 2023 first event - HCG 80%, CO2 80%. 2. Confirmed finding on an interview with Technical Consultant on 3/7/2023 about 3:45 P.M.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems

	identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on the review of Standard Operating Procedure (SOP), the laboratory failed to establish following as part of SOP. Findings: 1. Quality Assurance (QA) policy failed to include specimen submission and handling problems, complaints, communication problems with ordering providers, and personnel competency assessments as part of Quality Assurance (QA) records. 2. Specimen Transport policy 6.5.1 failed to establish temperature ranges and specific time frames appropriate for specimen transportation. 3. As per laboratory's T.A.T. Turnaround Time 6.8, the laboratory failed establish specific turnaround time for testing. 4. Confirmed finding on an interview with Technical Consultant on 3/7/2023 about 2:30 P.M.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on absence of the reference laboratory's manual and confirmed finding on an interview with the technical supervisor #2 on 3/7/2023 about 12:45 P.M, the laboratory failed to retain a copy of the Sherman Abrams Labs instruction manual. Section (5) Health Ex courier service obtains specimens from the 10 site locations. -Two blue coolers for room temperature samples and one red cooler for refrigerated samples. -No specimen pickup and drop off temperature logs were available at the time of the survey. -No cooler temperature validations were available at the time of the survey. -Surveyor reviewed a copy of the courier service log sheets which were emailed at the end of the day. -Courier log sheets did not document number of specimens picked up at each site location.
D5315	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(c) The laboratory must refer a specimen for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS. This STANDARD is not met as evidenced by: Based on review of Standard Operating Procedure, the laboratory failed to ensure that reference laboratory, Sherman Abrams, had a current, valid CLIA certificate. CLIA certificate was not available for review at the time of onsite survey. Confirmed finding on an interview with Technical Supervisor #2 on 3/7/2023 about 11:00 A.M.
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 lack of temperature log and humidity documentation, the laboratory failed to follow manufacturer's requirement for following analyzers. Findings: 1. The following analyzer temperature and humidity requirements were not monitored and documented: a. ThinPrep Review Scope: Operation temperature range 16?-32?, operating humidity range 20%-80%. b. Imager Duo: Operating temperature range 16?-32?, operating humidity range 20%-80%. c. Panther System: Operating temperature range 15?-30?, operating humidity range 20%-85%. d. Prisma Plus: Operating temperature range 10?-40?, operating humidity range 30%-85%. e. Liaison XL: Operating temperature range 15?-32?, operating humidity range 10%-85%. 2. The laboratory modified the humidity range to 20%-80% from the original humidity range 40%-80%. As per manufacturer instructions, "when using this modified specification, an anti-static floor mat must be placed in the workspace in front of the analyzer." The laboratory failed to place anti-static floor mat as required. 3. No documentation of Thermo Pro thermometer(s) calibration and serial number. Surveyor observed documented room temperatures and humidity however, the lab failed to record the temperatures and humidity from 11/11/21 through the survey date for all three specimen processing rooms and two storage rooms. 4. Surveyors observed no thermometer in room utilized for storage of specimen containers and transfer kits. 5. No documentation of temperatures for the storage room utilized storage of Molecular supplies and Hologic Panther. a. Five boxes Aptima Geno Typing kit: Temperature range 15?-30? - Lot # 337213B exp. 8/15/24. b. Two boxes Apitma Combo CV/TV: Temperature range 15?-30? lot # 464906A exp 3/15/24. c. One box Apitma TV: Temperature range 15?-30? lot# 402946A exp. 3/25/24. d. One box Apitma CV. Temperature range 15?-30? lot# 455884B exp 2/15/24. e. Fifty patient specimen testing tubes and thirty-three specimen test tubes. 6. Storage room for lab supplies. a. One box Multistix specimen swabs: Temperature range 15?-30?. b. Forty-eight boxes Apitma Auto Detect kit: Temperature range 15?-30? lot 329826 exp 6/15/24. c. Sixty-eight boxes of the combo wash solution, oil. Temperature range 15?-30? assay fluid lot #3275577 exp 6/15/24. 7. One bottle of Cytoseal 60 Lot# 533367 Expiration 04/2022. 8. Confirmed finding on an interview with Technical Consultant on 3/7/2023 about 3:00 P.M.
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 direct observation of reagent bottles stored in the flammable reagent storage cabinet, the laboratory failed to properly identify the reagent, concentration, lot number, expiration date, and storage requirement. Findings: 1. 90%, 70%, and 50% alcohol did not include storage temperature requirements and hazmat labels. 2. Confirmed finding on an interview with Technical Supervisor #2 on 3/7/2023 about 11:30 A.M.
D5633	CYTOLOGY CFR(s): 493.1274(d)(1) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening. This STANDARD is not met as evidenced by: Based on the review of cytologist workloads, the technical supervisor #2 failed to review and sign cytologist workload records for cytologist #3 on October 2022 and cytologist #4 on February 2023. Confirmed finding on an interview with Technical Supervisor #2 on 3/7/2023 about 1:00 P.M.
D5637	CYTOLOGY CFR(s): 493.1274(d)(1)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary. This STANDARD is not met as evidenced by: Based on the lack of cytologist workloads 6 months review, the laboratory failed to reassess at least every 6 months and adjust workload when necessary. Confirmed finding on an interview with Technical Supervisor #2 on 3/7/2023 about 11:30 A.M.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on the review of Quality Control (QC) Levy Jennings, the laboratory failed to perform corrective action for QC results trending above or below the prescribed mean. Findings 1. QC reviewed 01/01/2023 - 01/30/2023. a. Level 1: o SHGB QC trended below the mean. o SNSE2 QC trended below the mean. o FSH QC trended below the mean. o TSH QC trended above the mean. b. Level 2: o Prolactin QC trended below

	the mean. o T Uptake QC trended above the mean. o FSH QC trended below the mean. c. Level 3: o LH QC trended above the mean. o Prolactin QC trended below the mean. o T uptake QC trended above the mean. o Testosterone QC trended above the mean. o T3 QC trended above the mean. o T4 QC trended below the mean. 2. QC reviewed 10/1/2022 - 10/31/2022. a. Level 1: o Sex Hormone SHBG QC trended below the mean. o Folate QC trended below the mean o FT4 QC trended below the mean. o FSH QC trended below the mean o LH QC trended above the mean. o Testosterone QC trended above the mean. d. Level 2: o Progesterone QC trended above the mean. o Total Protein QC trended below the mean. o ALP QC trended below the mean. o Glucose QC trended below the mean. o K QC trended above the mean
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on the review of laboratory policies and procedures, and laboratory records, the laboratory director, technical consultant/technical supervisor#1, and technical supervisor #2, failed to be responsible for the overall operation and administration of the laboratory, to include assuring compliance with the applicable regulations and ensuring that all the duties of the laboratory director were performed. Refer to D3001, D5211, D5291, D5311, D5315, D5413, D5415, D5633, D5637, D5783
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on the review of API Proficiency records, the lab director failed to perform corrective action proficiency scores less than 100%, Refer to D5211
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 the lack of corrective action of QC reviews and confirmed in an interview with the technical consultant/technical supervisor#1 on the day of the survey, the laboratory director failed to ensure that the QC program for histopathology was followed to assure quality laboratory services. Refer to D5783
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 the review of laboratory policies and procedures, and laboratory records, the laboratory director, technical consultant/technical supervisor#1, and technical supervisor #2, failed to quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Refer to D3001, D5211, D5291, D5311, D5315, D5413, D5415, D5633, D5637, D5783
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on the review of Quality Control Levy Jennings, the technical supervisor #1 failed to establish a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance. Refer D5783
D6130	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3) (c) In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary. This STANDARD is not met as evidenced by: Based on the lack of cytologist workloads six-month reviews, the technical supervisor #2 failed to reassess the workload limit for each individual examining slides at least every six months and adjust workload as necessary. Confirmed finding on an interview with Technical Supervisor #2 on 3/7/2023 about 11:30 A.M.