Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0155899	01/27/2020
Name of Provider or Supplier	**Street Address, City, State**	
Babylon Medical Practice Pc	350 West Main Street, Babylon, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on surveyor review of the twice per year verification records and confirmed in an interview with the Laboratory Director/Technical Supervisor, the laboratory failed to verify the accuracy of interpretation of urine cytology and FISH testing at least twice per year in calendar year 2018.
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 surveyor review of the pathology laboratory's procedure manual and interview with the Laboratory Director/Technical Supervisor, the laboratory failed to establish written procedures for: 1. Policy and procedure for unacceptable specimens such as inadequate requisition information and mislabeled/unlabeled specimens; 2. A procedure describing laboratory's turnaround time for the urine cytology, thyroid FNA and FISH from sample collection to processing and to when final diagnosis is determined by the pathologist and entered into the lab computer system; 3. Retention of FISH images. 4. Policy for retention and storage of urine cytology and thyroid FNA slides; 5. Entering patient pathology results into the laboratory computer system and the procedure to be followed if the computer system is inoperable; 6. Twice per year verification and remediation of any discrepant results found during the twice yearly verification of urine cytology, thyroid FNA and FISH testing; 7. Acceptability of the staining characteristics of the Hematoxylin & Eosin (H & E) stain, special stain, Immunohistochemistry (IHC) stain and Papanicolaou (PAP) stain. 8. Preventive maintenance of the laboratory's microscope
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 surveyor review of microscope maintenance records and an interview with the Laboratory Director at the time of this survey, the laboratory failed to follow the manufacturer maintenance requirement. Findings include: The manufacturer of the microscope require annual preventive maintenance of the microscope used for urine cytology slides reading and thyroid FNA slides reading. The record of preventive maintenance was not available at the time of survey for the microscope for calendar year 2018. Approximately 200 patient slides were interpreted and reported for urine cytology and thyroid FNA during this time frame.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of quality control records and an interview with the Laboratory Director/Technical Supervisor at the time of this survey, the Laboratory Director

	failed to review and document the quality control acceptability of the staining characteristics of the Hematoxylin & Eosin (H & E) stain, Immunohistochemistry (IHC) stain, Papanicolaou (PAP) stain and failed to document the acceptability of the stained images for FISH testing on each day of reading from March 2018 through October 2018. Approximately 200 patients' urine cytology slides, FISH images and thyroid FNA slides were read and reported during this time period.
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 surveyor's review of the pathology laboratory procedure manual, lack of laboratory documents, interview and confirmation with the current Laboratory Director/Technical Supervisor, the laboratory failed to follow laboratory's written procedures to ensure that the Technical Supervisor established workload limits for the pathologist when performing primary screening of the non-gynecologic specimens from March 2018 through December 2019. Approximately 50 non-gynecologic cytology slides were reviewed and reported during this time frame.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor findings and interview with the Laboratory Director/Technical Supervisor, the Laboratory Director failed to provide overall management of the pathology laboratory. The Laboratory Director failed to ensure that the laboratory: 1. QC programs for urine cytology, FISH and thyroid FNA were maintained, refer to D6093; 2. QA program for urine cytology, FISH and thyroid FNA were maintained, refer to D6094.
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 a surveyor review of Quality Control (QC) records, and confirmed in an interview with the Laboratory Director on the day of the survey, the laboratory

	director failed to ensure that the QC program for urine cytology, FISH and thyroid FNA testing was followed to assure the quality of laboratory services. Refer to D5601, D5633
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 an interview with the Laboratory Director/Technical Supervisor, the laboratory failed to establish a written Quality Assessment (QA) policy/procedure for an on going mechanism to monitor, assess and when indicated correct problems identified in the general laboratory system as part of the laboratory's overall quality program. Refer to: D5217, D5403. D5429