| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 33D2005147 | 09/08/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Middletown Medical Pc | 2142 Route 302 Suite 103, Circleville, 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 |
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| **D5032** | CYTOLOGY<br>CFR(s): 493.1221<br><br>If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1274, and 493.1281 through 493.1299.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of laboratory policies and procedures, laboratory records and confirmed in an interview with the pathologist/technical supervisor, the laboratory failed to establish, reassess and document a workload limit for the laboratory director /technical supervisor (refer to D5633, D5637, D5639, D5641, D5645 and D5647);the pathologist failed to perform and document the quality control (QC) acceptability of the Hematoxylin and Eosin (H & E), special stains and immunostain stain used for histopathology slides (refer to D5601). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results in the subspecialty of Histology and Cytology. |
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the twice year verification records for histology and an interview with the pathologist/technical supervisor, the laboratory failed to verify the accuracy for the urine cytology from June 3, 2021 through September 8, 2022. FINDINGS: The pathologist/technical supervisor confirmed on September 8, 2022 at approximately 10: |

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| | 30 AM that the laboratory failed to verify the accuracy for the urine cytology from January 1, 2021 through September 8, 2022. a. Approximately 400 cases were reported during this time period. |
| **D5291** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Quality Assessment (QA) policy and a interview with the pathologist/technical supervisor, the laboratory failed to follow their establish QA policy and perform a annual QA review for the calendar year 2021. FINDINGS: 1. The laboratory to follow their establish QA policy and perform a annual QA review for the calendar year 2021. a. 2021 annual QA review documentation was not available for review. 2. The pathologist/technical supervisor, confirmed on September 8, 2022 at approximately 11:00 AM, the laboratory failed to follow their establish QA policy and perform a annual QA for 2021. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the previous Cytology manual, lack of Cytology Standard Operations Procedures (SOP) and an interview with the pathologist/technical supervisor, the laboratory failed to have a complete Cytology SOP to include the following criteria: for the detection of inadequately prepared slides, control procedures for the stained cytology slide, corrective action for unacceptable slides and establish a workload limits. FINDINGS: 1. The laboratory failed to have a complete Cytology SOP manual to include the following criteria: for the detection of |

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| | inadequately prepared slides, control procedures for the stained cytology slide, corrective action for unacceptable slides, establish Cytology workload limits. 2. The pathologist/technical supervisor confirmed on August 8, 2022 at 10:15 AM the above findings. |
| **D5407** | PROCEDURE MANUAL<br>CFR(s): 493.1251(d)<br><br>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's SOP manual and an interview pathologist /technical supervisor, the laboratory failed to have a Cytology procedure manual that is up-to-date and approve (sign and date) by the current laboratory director. FINDINGS: 1. The Cytology SOP manual that contain procedures from the previous laboratory director was not approved, signed and dated by the current laboratory director, who assumed this position on May 1, 2021. 2. The current Cytology procedure manual still lists the previous procedures that were approved by the previous laboratory director. |
| **D5601** | HISTOPATHOLOGY<br>CFR(s): 493.1273(a)(f)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the form titled "Quality Control" used to record the QC for the histology sidles and an interview with the pathologist/technical supervisor, the laboratory director/pathologist failed to record the acceptability of the control slides for the immunostain's, special stains and H & E from January 10, 2022 through August 23, 2022. FINDINGS: 1. The QC form used to record the pathologist(s) evaluation and the acceptability of the control slides for the immunostain's, special stains and H & E. Revealed that the laboratory director/pathologist failed to document the QC on the log sheet from January 10, 2022 through August 23, 2022 a total of 57 days. a. The pathologist(s) did not records the control results for 19 days during this time. 2. The pathologist/technical supervisor confirmed on August 8, 2022 at approximately 11:15 AM that the laboratory director/pathologist failed to record the acceptability of the control slides for the immunostain's, special stains and H & E from January 10, 2022 through August 23, 2022. |
| **D5633** | CYTOLOGY<br>CFR(s): 493.1274(d)(1)<br><br>(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a |

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| | maximum workload limit for each individual who performs primary screening.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the P SOP manual, lack of laboratory documents, and an interview with the pathologist/technical supervisor, the laboratory failed to establish written procedures for the maximum workload limit for each pathologist(s) when performing primary screening of the non-gynecologic specimens from May 1, 2021 through August 8, 2022. Approximately 400 non-gynecologic cytology slides were reviewed and reported during this time frame. Refer to D6130 |
| **D5637** | CYTOLOGY<br>CFR(s): 493.1274(d)(1)(ii)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Pathology SOP manual, lack of cytology workload records and an interview with the pathologist/technical supervisor, the laboratory failed to established written policies and procedures to ensure that workload limits would be reassessed at least every 6 months and adjusted when necessary for the two pathologist (s) who perform the primary screening of non-gynecologic cytology slides.<br>FINDINGS: The pathologist/technical supervisor, confirmed on August 8, 2022 at approximately 11:00 AM, that the laboratory failed to established written policies and procedures to ensure that workload limits would be reassessed at least every 6 months and adjusted when necessary for the two pathologist(s) who perform the primary screening of non-gynecologic cytology slides. Refer to D6130 |
| **D5639** | CYTOLOGY<br>CFR(s): 493.1274(d)(2)(i)<br><br>(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the Following: (d)(2) The maximum number of slides examined by an individual in each 24-hour period does not exceed 100 slides (one patient specimen per slide; gynecologic, nongynecologic, or both) irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and must not be employed as an individual's performance target. In addition-- (d)(2)(i) The maximum number of 100 slides is examined in no less than an 8-hour workday;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Pathology SOP manual and an interview with the pathologist /technical supervisor, the laboratory failed to establish written policies and procedures to ensure that the maximum number of slides examined in a 24-hour period does not exceed 100 slides regardless of the site or location. FINDINGS: The pathologist /technical supervisor confirmed on August 8, 2022 at approximately 11:05 AM, that the laboratory failed to establish written policies and procedures that ensure the maximum number of slides examined in a 24-hour period does not exceed 100 slides regardless of the site or location. Refer to D6130 |
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| **D5641** | CYTOLOGY<br>CFR(s): 493.1274(d)(2)(ii)<br><br>(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula-- Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of Pathology SOP manual and an interview with the pathologist /technical supervisor, the laboratory failed to establish written policies and procedures to ensure that the workload limit for the two pathologist(s), when examining slides in less than an 8-hour workday. FINDINGS: The pathologist/technical supervisor confirmed on August 8, 2022 at approximately 11:05 AM that the the laboratory failed to establish written policies and procedures to ensure that the workload limit for the two pathologist(s), when examining slides in less than an 8-hour workday would be prorated using a period of eight hours to determine the number of slides that may be examined. a. The formula-to be used to establish the workload limits is as follows: Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined. Refer to D6130 |
| **D5645** | CYTOLOGY<br>CFR(s): 493.1274(d)(3)<br><br>(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Pathology SOP manual, lack of workload records for both pathologist(s) and an interview the pathologist/technical supervisor, the pathologist(s) failed to record the number of hours spent examining the cytology slides from May 1, 2021 through August 8, 2022. FINDINGS: 1. The pathologist/technical supervisor confirmed on August 8, 2022 at approximately 11:30 AM, the surveyor's findings that the two pathologist(s), as the primary reader(s), failed to record the total number of slides examined in a 24-hour period and the number of hours spent examining slides from May 1, 2021 through August 8, 2022. 2. The pathologist stated, "that the number of slides screened and the hours screened, were not documented for this location and other sites." Refer to D6130 |
| **D5647** | CYTOLOGY<br>CFR(s): 493.1274(d)(4)<br><br>(d) Workload limits.The laboratory must establish and follow written policies and procedures that ensure the following: (d)(4) Records are available to document the workload limit for each individual. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of Pathology SOP manual, lack of workload limit records and confirmed in a interview with the pathologist/laboratory director/technical supervisor , at the time of this survey, the laboratory failed to establish written policies and procedures to ensure that records are maintained and available to document the workload for the individual who performs primary screening of non-gynecologic cytology slides. Redfer to D6130 |
| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of the pathology laboratory procedure manual and an interview with the pathologist/technical supervisor, the laboratory director failed to ensure overall management of the laboratory. The laboratory director failed to ensure that the: a. QC program was maintained, Refer to D6093: b. QA program was maintained, refer to D6094; c. Histology and Cytology procedure manual was complete and approved, refer to D6106; d. workload list was assessed every six months, refer to D6130; |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of Pathology SOP manual, histopathology QC records and confirmed in an interview with the pathologist/technical supervisor, the laboratory director failed to ensure that the established histology quality control program was maintained to assure the quality of histology and cytology testing and identify failures. Refer to D5601 |
| **D6094** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of Pathology SOP manual, QC records, lack of workload limit documentation and confirmed in an interview with the pathologist/technical supervisor, the laboratory director failed to ensure that quality assessment (QA) |

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| | programs were maintained to assure the quality of laboratory services and identify failures in quality as they occur. Refer to D5291 |
| **D6106** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(14)<br><br>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Pathology SOP manual and an interview with the pathologist /technical supervisor, the laboratory director failed to ensure the Histology and Cytology SOP manuals were completed and evaluated. Refer to D5403 and D5407 |
| **D6130** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(c)(2)(3)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Pathology SOP manual, lack of laboratory records and interview with the pathologist/technical supervisor, the technical supervisor failed to establish workloads limits for both pathologist's, as the primary readers, and failed to reassess the workload limits at least every six months and make adjustments when necessary. Refer to D5633, D5637, D5639, D5641 and D5647 |