Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D1057270	12/21/2023
Name of Provider or Supplier	**Street Address, City, State**	
Romius Institute Of Northwest Ohio Inc	3355 Meijer Dr, Toledo, OH	

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
D0000	A survey was completed on December 21, 2023. It was determined that Immediate Jeopardy (IJ) existed for the following condition level deficiencies: Laboratory Director- 42 CFR 493.1441 Technical Supervisor- 42 CFR 493.1447
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 review of 32 laboratory policies and procedures and interviews the laboratory failed to establish written policies and procedures for one laboratory test process. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the step-by-step process for

	reporting nongynecologic test results into the laboratory information system. 2. During an interview on December 5, 2023 at 10:15 AM, these findings were confirmed with the Technical Supervisor. 3. During an interview on December 5, 2023 at 2:50 PM, these findings were confirmed with the Office Manager.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of 32 laboratory policies and procedures and interviews the laboratory failed to ensure that 27 of 32 written policies and procedures were approved, signed and dated by the Laboratory Director. Findings include: 1. The Laboratory Director failed to sign and date 27 of 32 laboratory policies and procedures. Procedures include: -GOALS AND OBJECTIVES -SCOPE OF SERVICES -SAFETY -EQUIPMENT -MICROSCOPE -COMPUTERS -SECURITY -LABORATORY INFORMATION SYSTEM (LIS) -SOP -JOB DESCRIPTIONS & DUTIES -TRAINING & COMPETENCY EVALUATION -REQUISITION -SPECIMEN IDENTITY & INTEGRITY -SPECIMEN PROCESSING -SLIDE VERIFICATION -SLIDE QUALITY -REPORTING -TIMELINESS -CONFIDENTIALITY -PUBLIC HEALTH REPORTING -SLIDE HANDLING & FILING -REFERRALS & CONSULTATION REQUESTS -COMPETENCY REVIEW -PEER REVIEW -NOMENCLATURE FOR NON-GYNECOLOGICAL CYTOLOGY (URINE CYTOLOGY) PERTINENT LITERATURE REFERENCE FOR TERMINOLOGY -REPORT CORRECTION OR AMENDMENT -CYTOLOGY WORKLOAD LIMIT POLICY 2. During an interview on December 5, 2023 at 10:15 AM, these findings were confirmed with the Technical Supervisor. 3. During an interview on December 5, 2023 at 2:50 PM, these findings were confirmed with the Office Manager.
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory statistical records and interviews the laboratory failed to follow written policies and procedures for the

	evaluation and comparison of one of three nongynecologic cytology statistics. The laboratory failed to document one of three required annual nongynecologic statistics for 2021 and 2022. Findings include: 1. The laboratory failed to follow an untitled procedure which stated: "A non-gynecological cytology diagnosis summary report is prepared on an annual basis to display statistics, including case number, types and diagnosis". 2. The Survey Team requested and the laboratory failed to provide one of three required annual nongynecologic cytology statistics for 2021 and 2022. Statistic includes: -The number of nongynecologic cytology cases examined 3. During an interview on December 5, 2023 at 10:15 AM, these findings were confirmed with the Technical Supervisor. The Technical Supervisor stated "the computer report does not give a total." 4. During an interview on December 5, 2023 at 2:50 PM, these findings were confirmed with the Office Manager.
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 review of laboratory policies and procedures, laboratory records and cytology specimen slide preparations the laboratory failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The Laboratory Director failed to ensure quality assessment programs were established to assure the quality of laboratory services and identify failures in quality as they occur (refer to D6094); and failed to ensure the competency of one of one Technical Supervisors (refer to D6103).
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 review of laboratory policies and procedures, laboratory records and cytology specimen slide preparations the Laboratory Director failed to ensure quality assessment programs were established and followed to identify, monitor and assess the quality of the analytic cytology services. The Laboratory Director failed to identify one of 28 cytology slide preparations as having a diagnostic error as part of their urine cytology quality assurance (QA) program from 2021 and 2022, and failed to establish programs to identify 25 diagnostic errors from January 2019 through November 2023. Findings include: 1. The Laboratory Director failed to ensure the establishment of written policies and procedures for an effective quality assessment program to ensure the accuracy of diagnostic interpretations. a. The procedure titled PEER REVIEW stated: "Bi-annually, a random selection of 2% or (at least 6 cases cytology) reviewed by the facility during that time period will be re-screened by an appropriate specialized pathologist other than the sign out pathologist." b. The peer review program failed to be effective in ensuring the accuracy of diagnostic

	interpretations for one of one Technical Supervisors. 2. The Survey Team reviewed 28 cytology specimen slide preparations and the corresponding final test reports from the laboratory's peer review program from 2021 and 2022. The peer review program failed to identify one of 28 cytology specimen slide preparations as being discrepant. Case includes: -PLC22-5684 Cystocopy Urine 10/07/2022 LABORATORY DIAGNOSIS: Atypia, Inconclusive FACILITY B DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Urothelial Carcinoma 3. The Laboratory Director failed to establish and follow programs to identify 25 diagnostic errors from January 2019 through November 2023. Refer to D6115
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of laboratory polices and procedures, laboratory records and cytology specimen slide preparations the Laboratory Director failed to establish and follow written policies and procedures to ensure the competency of the Technical Supervisor to accurately report diagnostic interpretations. The Laboratory Director failed to identify and document needs for remedial training to improve upon the diagnostic skills of one of one Technical Supervisors in 2021, 2022 and January 2023 to the date of the survey. Findings include: 1. The Survey Team requested and the Laboratory Director failed to provide written policies and procedures to ensure the competency of the Technical Supervisor to report urinary cytology specimens, to identify the Technical Supervisor's need for remedial training and to improve upon the Technical Supervisor's diagnostic skills to identify and report the following diagnostic entities: (Refer to D6115) -High Grade Urothelial Carcinoma -Suspicious for High Grade Urothelial Carcinoma 2. The Survey Team requested and the Laboratory Director failed to provide documentation of the need for remedial training to improve upon diagnostic skills for one of one Technical Supervisor when reporting urine cytology specimens in 2021, 2022 and January 2023 to the date of the survey. Technical Supervisor includes: -Technical Supervisor
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of 347 nongynecologic cytology cases/slides and corresponding final test reports the laboratory failed to have a Technical Supervisor who meets the qualification requirements of 493.1451 of this subpart. The Technical Supervisor failed to verify the accuracy of 25 nongynecologic cytology tests (refer to D6115).

D6115

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(2)

The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:
A. Based on microscopic review of 209 random negative nongynecologic cases/slides and corresponding final cytology test reports from January 2019 through November 2023 and confirmation by the Survey Team Pathologist on December 21, 2023 the Technical Supervisor failed to verify the accuracy of three nongynecologic cytology tests. 1. PLC22-6687 11/19/2022 Voided Urine LABORATORY DIAGNOSIS: Negative for High Grade Urothelial Carcinoma SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for High Grade Urothelial Carcinoma 2. PLC23-217 01/14 /2023 Voided and Cystoscopy Urine LABORATORY DIAGNOSIS: Negative for Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for High Grade Urothelial Carcinoma 3. PLC23-1870 04/24/2023 Voided Urine LABORATORY DIAGNOSIS: Negative for Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for High Grade Urothelial Carcinoma B. Based on microscopic review of 138 random non-negative nongynecologic cases /slides and the corresponding final cytology test reports from January 2019 through November 2023 and confirmation by the Survey Team Pathologist on December 21, 2023 the Technical Supervisor failed to verify the accuracy of 22 nongynecologic cytology tests. 1. PLC22-5684 10/07/2022 Cystoscopy Urine LABORATORY DIAGNOSIS: Atypia, Inconclusive SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Urothelial Carcinoma 2. PLC23-174 01/14/2023 Cystoscopy Urine LABORATORY DIAGNOSIS: Atypical Urothelial Cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Urothelial Carcinoma 3. THY19-2833 03 /18/2019 Cystoscopy Urine LABORATORY DIAGNOSIS: Carcinoma, Papillary Urothelial SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for High Grade Urothelial Carcinoma 4. THY19-3145 03/25/2019 Cystoscopy Urine LABORATORY DIAGNOSIS: Carcinoma, Papillary Urothelial SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for High Grade Urothelial Carcinoma 5. THY19-3693 04/05 /2019 Voided and Cystoscopy Urine LABORATORY DIAGNOSIS: Carcinoma, Papillary Urothelial SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for High Grade Urothelial Carcinoma 6. THY19-4067 03/18/2019 Cystoscopy Urine LABORATORY DIAGNOSIS: Carcinoma, Papillary Urothelial SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for High Grade Urothelial Carcinoma 7. THY19-7368 07/01/2019 Voided Urine LABORATORY DIAGNOSIS: Carcinoma, Papillary Urothelial SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for High Grade Urothelial Carcinoma 8. THY19-9006 08/08/2019 Cystoscopy Urine LABORATORY DIAGNOSIS: Carcinoma, Papillary Urothelial SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for High Grade Urothelial Carcinoma 9. THY19-13558 11/20/2019 Cystoscopy Urine LABORATORY DIAGNOSIS: Carcinoma, Papillary Urothelial SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for High Grade Urothelial Carcinoma 10. THY20-2656 03/06/2020 Bladder Wash LABORATORY DIAGNOSIS: Carcinoma, Papillary Urothelial SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for High Grade Urothelial Carcinoma 11. THY20-5891 06/04/2020 Cystoscopy Urine LABORATORY DIAGNOSIS: Carcinoma, Papillary Urothelial SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for High Grade Urothelial Carcinoma 12. THY20-7005 06/26

	/2020 Voided Urine LABORATORY DIAGNOSIS: Carcinoma, Papillary Urothelial SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for High Grade Urothelial Carcinoma 13. THY20-7246 07/02/2020 Voided Urine LABORATORY DIAGNOSIS: Carcinoma, Papillary Urothelial SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for High Grade Urothelial Carcinoma 14. THY20-10655 10 /16/2020 Voided Urine LABORATORY DIAGNOSIS: Carcinoma, Papillary Urothelial SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for High Grade Urothelial Carcinoma 15. THY20-10973 10/29/2020 Voided Urine LABORATORY DIAGNOSIS: Carcinoma, Papillary Urothelial SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for High Grade Urothelial Carcinoma 16. THY20-11120 11 /03/2020 Cystoscopy Urine LABORATORY DIAGNOSIS: Carcinoma, Papillary Urothelial SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for High Grade Urothelial Carcinoma 17. THY20-11893 12/04/2020 Cystoscopy Urine LABORATORY DIAGNOSIS: Carcinoma, Papillary Urothelial SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for High Grade Urothelial Carcinoma 18. THY20-12346 12/23/2020 Voided Urine LABORATORY DIAGNOSIS: Carcinoma, Papillary Urothelial SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for High Grade Urothelial Carcinoma 19. THY21-5875 05/17/2021 Bladder Wash LABORATORY DIAGNOSIS: Carcinoma, Papillary Urothelial SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for High Grade Urothelial Carcinoma 20. THY19-13974 11/29/2019 Cystoscopy Urine LABORATORY DIAGNOSIS: Suspicious for Papillary Urothelial Neoplasm SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for High Grade Urothelial Carcinoma 21. THY20-10190 09 /29/2020 Cystoscopy Urine LABORATORY DIAGNOSIS: Suspicious for Papillary Urothelial Neoplasm SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for High Grade Urothelial Carcinoma 22. THY20-12296 12/23/2020 Bladder Wash LABORATORY DIAGNOSIS: Suspicious for Papillary Urothelial Neoplasm SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for High Grade Urothelial Carcinoma
D9999	By agreement between ASCT Services, Inc. and CMS, information provided for CMS's completion of CMS Form 670 are ASCT Services, Inc. averages only. This information is confidential and proprietary to ASCT Services, Inc., is exempt under the Freedom of Information Act (5 U.S.C. 552 et seq.), and shall be used for federal government purposes only.