Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0205041	12/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
Center For Urologic Care Of Berks Cnty	1320 Broadcasting Road, Suite 200, Wyomissing, PA	

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
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 review of laboratory policies and procedures, competency assessment records and interview with the Laboratory Director/Technical Supervisor #1, the laboratory failed to establish and follow written policies and procedures to assess the competency of the Technical Supervisors. The laboratory failed to assess the competency for two of two Technical Supervisors in 2021, 2022 and January 2023 to the date of the survey in 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the process to assess the competency of the Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for two of two Technical Supervisors in 2021, 2022 and January 2023 to the date of the survey in 2023. Technical Supervisors include: -Laboratory Director/Technical Supervisor #1 -Technical Supervisor #2 3. During an interview on December 6, 2023 at 11:15 AM these findings were confirmed by the Laboratory Director/Technical Supervisor #1.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242.

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview with the Laboratory Director/Technical Supervisor #1, the laboratory failed to follow it's procedure to assess the accuracy of entering patient information into the laboratory information system from January 2022 to December 2022 and January 2023 to the date of the survey in 2023. Findings include: 1. The laboratory procedure ACCESSIONING ACCURACY REVIEW stated: - Each quarter 10 requisitions received the previous quarter are randomly pulled from the file. - The corresponding reports are printed. - The information on the report and requisition are compared for accuracy and typographical errors. - The discrepancies are reported and discussed at the monthly quality assurance meeting. - Corrective action will be the responsibility of the supervisor, practice administrator and/or the pathologist. 2. The Survey Team requested and the laboratory failed to provide documentation of a quarterly accessioning review of ten requisitions and corresponding final reports from January 2022 to December 2022 and from January 2023 to the date of the survey in 2023. 3. During an interview on December 6, 2023 at 11:15 AM these findings were confirmed by the Laboratory Director/Technical Supervisor #1.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of 17 laboratory policies and procedures, laboratory records and interview with the Laboratory Director/Technical Supervisor #1, the laboratory failed to follow two written policies and procedures. Findings include: 1. The laboratory failed to follow the procedure IN HOUSE PROFICIENCY PROGRAM FOR URINE CYTOLOGY AND PATHOLOGY, which stated: - Twice a year, the supervisor will randomly choose 14 urine cytology slides and 21 surgical pathology cases. - Each slide will be assigned a proficiency test number and will be labeled accordingly. - a copy of the original report will be used by the supervisor to provide some patient data such as age, sex and pre-operative diagnosis. - The supervisor will give the slide set and the recording form to the pathologist. - The supervisor will be responsible for reviewing the results, recording them on the Cytology Proficiency Comparison Log and determining the results are acceptable and unacceptable. - An acceptable score is achieved when all the reading pathologists interpret the slides in an equivalent manner. a. The Survey Team requested and the laboratory failed to provide documentation of the Cytology Proficiency Comparison Form for January 2022 through December 2022 and January 2023 to the date of the survey in 2023. 2. The laboratory failed to follow the procedure PATHOLOGISTS STATISTICS which stated: - The senior lab staff member will compile the statistics on each pathologist according to diagnostic categories for each major specimen source. - All pathologist acting as a primary screener will have the results of their proficiency tests compiled. - the statistics on case referrals and consultations will be compiled. - The consultation review-discrepancy report will be compiled and presented annually in a report to the practice physicians for review. - Trends will be monitored and compared to

	pathologists in similar practices as appropriate. - Recommendations will be made for continuous quality improvement. a. The Survey Team requested and the laboratory failed to provide documentation of the review-discrepancy report. 3. During an interview on December 6, 2023 at 11:15 AM these findings were confirmed by the Laboratory Director/Technical Supervisor #1.
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 review of laboratory policies and procedures and interview with the Laboratory Director/Technical Supervisor #1, the laboratory failed to establish and follow written policies and procedures to establish an individual maximum workload limit for each Technical Supervisor who performed primary screening of non-gynecologic cytology specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the Technical Supervisor would establish maximum workload limits for each Technical Supervisor who performed primary screening of non-gynecologic cytology specimens. 2. During an interview on December 6, 2023 at 11:15 AM these findings were confirmed by the Laboratory Director/Technical Supervisor #1.
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 review of laboratory policies and procedures and interview with the Laboratory Director/Technical Supervisor #1, the laboratory failed to establish and follow written policies and procedures to reassess and adjust when necessary, a maximum workload limit at least every six months for the Technical Supervisors who performed primary screening of non-gynecologic cytology specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the Technical Supervisor would reassess a maximum workload limit for the Technical Superviors at least every six months and adjust when necessary. 2. During an interview on December 6, 2023 at 11:15 AM these findings were confirmed by the Laboratory Director/Technical Supervisor #1.
D5647	CYTOLOGY CFR(s): 493.1274(d)(4) (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.

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of workload limit records and interview with the Laboratory Director/Technical Supervisor #1, the laboratory failed to establish and follow written policies and procedures to ensure records were available to document the workload limit for two of two Technical Supervisors who performed primary screening of non-gynecologic cytology specimens in January 2022 through December 2022 and January 2023 to the date of the survey in 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure records were available to document the workload limit for the Technical Supervisors who performed primary screening of non-gynecologic cytology specimens. 2. The Survey Team requested and the laboratory failed to provide records of individual workload limits for two of two Technical Supervisors who performed primary screening of non-gynecologic cytology specimens in January 2022 through December 2022 and January 2023 to the date of the survey in 2023. Technical Supervisors include: - Laboratory Director/Technical Supervisor #1 -Technical Supervisor #2 3. During an interview on December 6, 2023 at 11:15 AM these findings were confirmed by the Laboratory Director/Technical Supervisor #1.
D5655	CYTOLOGY CFR(s): 493.1274(e)(4) (e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, non-gynecologic cytology slide preparations, corresponding final test reports and interview with the Laboratory Director/Technical Supervisor #1, the laboratory failed to establish and follow written policies and procedures to ensure unsatisfactory non-gynecologic cytology slide preparations were identified and reported as unsatisfactory. The laboratory failed to identify and report one of two unsatisfactory non-gynecologic cytology cases from July 2023 to the date of the survey in 2023 as "Unsatisfactory for Evaluation." Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure unsatisfactory non-gynecologic cytology slide preparations were identified and reported as unsatisfactory. 2. The laboratory failed to identify and report one of two non-gynecologic cytology cases from July 2023 to the date of the survey in 2023 as being Unsatisfactory for Evaluation. (refer to D6115) Case includes: - CY23-961 3. During an interview on December 6, 2023 at 11: 15 AM these findings were confirmed by the Laboratory Director/Technical Supervisor #1.
D5657	CYTOLOGY CFR(s): 493.1274(e)(5) (e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(5) The report contains narrative descriptive nomenclature for all results.

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview with the Laboratory Director/Technical Supervisor #1, the laboratory failed to establish and follow written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report non-gynecologic cytology test results. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to define the criteria used and the system of narrative descriptive nomenclature used by the laboratory to report non-gynecologic cytology test results. 2. During an interview on December 6, 2023 at 11:15 AM these findings were confirmed by the Laboratory Director/Technical Supervisor #1.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview with the Laboratory Director/Technical Supervisor #1, the laboratory failed to establish and follow written policies and procedures for the laboratory's practice of obtaining a second technical supervisor's review of the diagnosis of non-gynecologic cytology specimen tests. Findings include: 1. The Survey Team requested and the laboratory failed to provide a written policy and procedure to detail the laboratory's program for the QA Report. a. The Survey Team was provided the laboratory's QA REPORT which documented the review of the initial diagnosis of non-gynecologic specimen slides by a second technical supervisor. 2. During an interview on December 6, 2023 at 11:15 AM these findings were confirmed by the Laboratory Director/Technical Supervisor #1.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of documentation and interview with the Laboratory Director/Technical Supervisor #1, the Laboratory Director failed to specify in writing the responsibilities and duties of the Technical Supervisors in 2022 and January 2023 to the date of the survey in 2023. Findings include: 1. The Survey Team requested and the Laboratory Director failed to provide written descriptions of the current responsibilities and duties for two of two Technical Supervisors. Technical Supervisors include: - Laboratory Director/Technical

	Supervisor #1 - Technical Supervisor #2 2. During an interview on December 6, 2023 at 11:15 AM these findings were confirmed by the Laboratory Director/Technical Supervisor #1.
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: Based on the microscopic review of 186 negative non-gynecologic cytology cases /slides from July 2023 to November 2023, the Technical Supervisor failed to verify the accuracy of one non-gynecologic cytology test. 1. C23-961 10/04/2023 ThinPrep Slide Voided Urine LABORATORY DIAGNOSIS: No atypical urothelial cells seen SURVEY TEAM DIAGNOSIS: Unsatisfactory, hypocellular TECHNICAL SUPERVISOR #1 DIAGNOSIS: Unsatisfactory, degenerated cellular material
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 workload limit records and interview with the Laboratory Director/Technical Supervisor #1, the Technical Supervisor failed to establish and reassess a maximum workload limit for two of two Technical Supervisors for January 2022 through December 2022 and January 2023 to the date of the survey in 2023. Findings include: 1. The Technical Supervisor failed to provide documentation that the Technical Supervisor established a maximum workload limit for two of two Technical Supervisors who performed primary nongynecologic cytology slide examinations for January 2022 through December 2022 and January 2023 to the date of the survey in 2023. Refer to D5633 and D5647. Technical Supervisors include: - Laboratory Director/Technical Supervisor #1 -Technical Supervisor #2 2. The Technical Supervisor failed to provide documentation that the Technical Supervisor reassessed a workload limit at least every six months for two of two Technical Supervisors who performed primary nongynecologic cytology slide examinations for January 2022 through December 2022 and January 2023 to the date of the survey in 2023. Refer to D5637 and D5647. Technical Supervisors include: - Laboratory Director/Technical Supervisor #1 -Technical Supervisor #2 3. During an interview on December 6, 2023 at 11:15 AM these findings were confirmed by the Laboratory Director/Technical Supervisor #1.
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