Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2006898	01/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
Clinical Pathology Associates	3445 Executive Center Dr, Suite 250, Austin, TX	

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	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of pre-survey paperwork, quality control (QC) records, test reports, interview, and query, the laboratory failed to document the intended reactivity to ensure predictable staining characteristics for the Papanicolaou (PAP) stain used in cytology screening and interpretations of GYN and non-GYN cases stained predictably for ten of ten months reviewed. Findings follow. A. Review of the pre-survey paperwork titled Annual Test Volume & Proficiency Testing Programs Worksheet showed cytology screening and interpretations of GYN and non-GYN cases began 04/01/2023. B. Quality control records for cytology were requested at 1540 hours on January 25, 2024 but not provided. C. The following test reports/cases with the PAP stain were reviewed: Accession # Date Reported 1. PAP23-001882 01 /19/2024 2. PAP23-002458 04/13/2023 3. PAP23-006043 07/20/2023 4. PAP23-006664 08/03/2023 5. PAP23-009469 10/10/2023 D. Interview with the General Supervisor on January 25, 2024 at 1540 hours by phone acknowledged the main lab that prepared the slides and performed the technical component did that and confirmed there was no documentation of the quality control for the PAP screening and interpretations performed at this location. E. Review of the file titled "PAP cases

	for Inspection 2023" showed the total GYN cases reported was 9,174 in 2023. Review of the file titled "2023 cases read at CPA" showed the total non-GYN cases was 13 in 2023. KEY: GYN = gynecological
D5631	CYTOLOGY CFR(s): 493.1274(c)(6) (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)(6) An evaluation of the case reviews of each individual examining slides against the laboratory's overall statistical values, documentation of any discrepancies, including reasons for the deviation, and, if appropriate, corrective actions taken. This STANDARD is not met as evidenced by: Based on review of pre-survey paperwork, interview, cytology statistics, email and query, the laboratory failed to evaluate the case reviews for each pathologist examining slides against the laboratory's overall statistical values to include the number of cases reported, the number of cases reviewed, and the number discrepant for one of one pathologist interpreting GYN and non-GYN cases in 2023. Findings follow. A. Review of the pre-survey paperwork titled Annual Test Volume & Proficiency Testing Programs Worksheet showed cytology screening and interpretations of GYN and non-GYN cases began 04/01/2023. B. Interview with the Clinical Service Manager on January 25, 2024 at 1520 hours acknowledged one of the pathologists interpreted most of the abnormal cytology cases. C. Cytology statistics for the evaluation of the case reviews of each pathologist examining slides against the laboratory's overall statistical values, the number of cases reported, the number of cases reviewed, and the number discrepant were requested on January 25, 2024 at 1520 hours and January 26, 2024 at 1110 hours but not provided. D. Email with the Clinical Service Manager on January 26, 2024 at 1526 hours confirmed they don't have cytology statistics for the pathologists to include the number of cases reviewed, and the number discrepant, only the raw data. E. Review of the file titled "PAP cases for Inspection 2023" showed the total GYN cases reported was 9,174 in 2023. Review of the file titled "2023 cases read at CPA" showed the total non-GYN cases was 13 in 2023. KEY: GYN = gynecological
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports, interview, and query, the laboratory failed to include the name and address of the facility where the cytology screening and/or

	interpretations were performed for five of five reports reviewed. Findings follow. A. Review of five test reports showed all five were missing the name and address of the facility where the Cytologic Diagnosis was performed: Accession # Date Reported 1. PAP23-001882 01/19/2024 2. PAP23-002458 04/13/2023 3. PAP23-006043 07/20 /2023 4. PAP23-006664 08/03/2023 5. PAP23-009469 10/10/2023 B. Interview with the Clinical Service Manager on January 25, 2024 at 1645 hours confirmed the PAP test reports did not have the name and address of the facility for testing performed at this location. C. Review of the file titled "PAP cases for Inspection 2023" showed the total GYN cases reported was 9,174 in 2023.
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 review of pre-survey paperwork, quality control (QC) records, test reports, interview, and query, the Laboratory Director failed to ensure a quality control (QC) program for the Papanicolaou (PAP) stain used in cytology screening and interpretations of GYN and non-GYN cases was established and maintained for ten of ten months reviewed (See D5473).
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 review of pre-survey paperwork, quality control (QC) records, test reports, interview, and query, the Technical Supervisor failed to establish a quality control (QC) program for the Papanicolaou (PAP) stain used in cytology screening and interpretations of GYN and non-GYN cases stained predictably for ten of ten months reviewed (See D5473).
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of pre-survey paperwork, personnel files and interview, the Technical Supervisor failed to evaluate the competency at least semiannually during

	the first year the individual tests patient specimens for one of two new cytotechnologists that performed screening in cytology. Findings follow. A. Review of the pre-survey paperwork titled Laboratory Personnel showed testing personnel #3 and 4 (as listed on the CMS form 209), were hired on 03/06/2023 and 05/08/2023, respectively. B. Review of the personnel file showed two Employee Performance Evaluations and the Core Competency/Demonstration Records were performed on 11 /03/2023 and 12/15/2023 for each cytotechnologist by the General Supervisor. Elapsed time for the initial competency evaluation for testing personnel #3 was 8 months. C. Interview with the General Supervisor on January 25, 2023 at 1315 hours by phone acknowledged that when he started in August [2023], he noticed the competency evaluations had not been done, so he performed them, and confirmed it was late for testing personnel #3.