Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0983381	07/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Cytology Associates Of Dayton Inc	One Wyoming Street, Dayton, 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
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 review of the laboratory's policies and procedures, proficiency testing (PT) documentation, and an interview with the Lab Director (LD) the laboratory failed to verify the accuracy of all unregulated analyte test procedures performed, at least twice annually. Findings Include: 1. Review of the laboratory's policies and procedures, provided on the date of the inspection, did not find any mention of a test accuracy verification policy and procedures. 2. The Surveyor requested the laboratory's test accuracy verification policy and procedures and 2017 and 2018 test accuracy verification or PT documentation for all unregulated analytes. The LD confirmed the laboratory did not establish a test accuracy verification policy and procedure for unregulated analytes. 3. The LD confirmed the laboratory was not enrolled in a PT program for unregulated analytes, and did not complete test accuracy verification for unregulated analytes. The interview occurred on 07/12/2018 at 10:30 AM.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, and an interview with the Laboratory Director (LD), the laboratory failed to establish and follow written policies and procedures for specimen acceptability and rejection. Findings Include: 1. Review of the laboratory's policy and procedure manual titled "Procedure Manual CLIA #36D0983381 for Cytology Associates of Dayton Inc." found no reference to specimen acceptability and rejection procedures. 2. The surveyor requested a policy and procedure for specimen acceptance and rejection including documentation from the LD on the date on the survey. The LD confirmed if specimens were rejected they were "walked across the hall and fixed" and there was no policy and procedure or documentation. The interview occurred on 07/12/2018 at 11:25 AM.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedures and an interview with the Laboratory Director (LD), the laboratory failed to have an approved corrective action plan established when any Proficiency Test (PT) results are found to be unacceptable. Findings were as follows: 1. Review of the laboratory manual titled "Procedure Manual CLIA #36D0983381 for Cytology Associates of Dayton Inc" found no PT corrective action policy and procedure. 3. The laboratory director confirmed no corrective action policy and procedure was established. The interview occurred on 07 /12/2018 at 10:30 AM.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on review of CMS form 209, the laboratory failed to have one or more general supervisors who were qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. Findings Include: 1. Review of CMS form 209 signed and dated by the LD on 07/12/2018, revealed the laboratory failed to establish a General Supervisor.
D6153	CYTOLOGY GENERAL SUPERVISOR CFR(s): 493.1467 For the subspecialty of cytology, the laboratory must have a general supervisor who meets the qualification requirements of 493.1469 of this subpart, and provides supervision in accordance with 493.1471 of this subpart.

	This CONDITION is not met as evidenced by: Based on review of CMS form 209, the laboratory failed to have one or more cytology general supervisors who were qualified under 493.1469 of this subpart to provide general supervision in accordance with 493.1471 of this subpart. Findings Include: 1. Review of CMS form 209 signed and dated by the LD on 07/12/2018, revealed the laboratory failed to establish a Cytology General Supervisor.