Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2020904	12/21/2022
Name of Provider or Supplier	**Street Address, City, State**	
Rolling Oaks Cytopathology Consultants Inc	18200 Sw 52 Court, Southwest Ranches, FL	

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 recertification survey conducted from 12/19/2022 to 12/21/2022 found the ROLLING OAKS CYTOPATHOLOGY CONSULTANTS INC clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following Conditions were cited: -D2000 Enrollment And Testing of Samples. -D6076 Laboratory Director.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on the lack of annual gynecologic cytology proficiency testing (PT) enrollment record and interview, the laboratory failed to enroll in an annual CMS-approved PT program for gynecologic cytology examination in 2021. Findings include: -Review of American Society for Clinical Pathology (ASCP) Proficiency Testing (PT) records revealed that the laboratory failed to enroll and participate in PT during 2021. During an interview on 12/19/2022 at 10:45 AM, the laboratory owner confirmed the findings.
D5645	CYTOLOGY CFR(s): 493.1274(d)(3)

	(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. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document the total number of slides the Cytotechnologist examined per 24-hour period and the number of hours he spent examining slides per 24-hour period in 18 out of 29 reading days reviewed from January to October of 2022. Findings include: -The form that the laboratory used to document the daily workload of the Cytotechnologist was the "DAILY QUALITY CONTROL FORM" (DQC). Review of the DQC revealed that the laboratory had to record the following information: " CYTOTECHNOLOGIST NAME, DATE, ACCESSION NUMBERS SCREENED, TOTAL CASES, TOTAL SLIDES, HOURS SPENT SCREENING (Exclude lunch and breaks), SLIDES SCREENED OUTSIDE". -Review of DQC forms from January to October 2022 revealed that during the following dates the laboratory failed to document the total slides examined and hours spent screening per period of 24 hours: 01/07/2022, 02/09 /2022, 02/10/2022, 02/17/2022, 03/30/2022, 03/31/2022, 04/14/2022, 04/18/2022, 06 /13/2022, 07/06/2022, 07/10/2022, 09/01/2022, 09/02/2022, 09/05/2022, 09/30/2022, 10/06/2022, 10/10/2022, 10/26/2022. During an interview on 12/19/2022 at 11:30 AM, the laboratory owner confirmed that the laboratory failed to document the total number of slides and the hours spent reading by the Cytotechnologist in the days of reference.
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 interview the laboratory failed to have a Laboratory Director (LD) who provides overall management and direction in accordance with 493.1445 of this subpart. The LD failed to ensure the laboratory enrolled in a CMS-approved annual gynecologic cytology Proficiency Testing (PT) program in 2021. Refer to D6088.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on the lack of annual gynecologic proficiency testing (PT) enrollment record for 2021 and interview, the Laboratory Director (LD) failed to ensure the laboratory enrolled in a PT program for 2021. Findings Include: -Review of American Society

	for Clinical Pathology (ASCP) Proficiency Testing (PT) records, revealed that the laboratory failed to enroll in PT for 2021. During an interview on 12/19/2022 at 10:45 AM, the laboratory owner confirmed the findings.