Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2118441	(X3) Date Survey Completed 07/23/2019
Name of Provider or Supplier Ron S Israeli, Md, Pc	**Street Address, City, State** 349 E Northfield Road, Suite 202, Livingston, NJ	

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
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 surveyor review of the Procedure Manual and interview with the Laboratory Consultant (LC), the laboratory failed to establish a written procedure which included patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation) from November 2018 to the date of the survey. The LC confirmed on 7/23/19 at 10:30 am the laboratory did not have the above procedure.
D5663	CYTOLOGY CFR(s): 493.1274(f)(4) (f) Record and slide retention. (f)(4) All slides must be retrievable upon request. This STANDARD is not met as evidenced by:

	Based on surveyor review of the Procedure Manual and interview with the Laboratory Consultant (LC), the laboratory failed to establish a written procedure to ensure return of slides from November 2018 to the date of the survey. The LC confirmed on 7/23/19 at 10:30 am the laboratory did not have the above procedure.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR), Shipping Manifest (SM) and interview with the Laboratory Consultant (LC), the Laboratory Director (LD) failed to ensure the timely reporting of Cytology results from November 2018 to the date of the survey. The findings include: 1. A review of the FR and SM revealed: a. A biopsy sample from 11/30/18 was reported 1/3/19. b. Biopsy samples from 12/10/18 to 12/20 /18 were reported 1/14/19. c. A biopsy sample from 2/8/19 was reported 3/10/19. d. Biopsy samples from 4/4/19 through 4/11/19 were reported 5/5/19. e. Biopsy samples from 4/30/19 through 5/8/19 were reported 6/23/19. 2. A total of 19 patient biopsies were received during the above time period. 3. The LC confirmed on 7/23/19 at 11:10 am the LD did not ensure test results were reported promptly.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on lack of a Procedure Manual (PM) and interview with the Laboratory Consultant (LC), the Laboratory Director (LD) failed to have an approved PM for the professional component of Histopathology from November 2018 to the date of the survey. The LC confirmed on 7/23/19 at 10:00 am that the LD did not ensure an approved PM was available.