Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2037437	(X3) Date Survey Completed 07/20/2022
Name of Provider or Supplier Partners In Specialty Pathology	**Street Address, City, State** 1045 Steeplechase Dr, Lancaster, 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
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with Laboratory Director (LD), on the day of survey the laboratory failed to retain histopathology patient test reports as required for 2 years from January 2020 through the date of inspection 07/20/2022. Findings include: 1. On the day of survey, 07/20/2022 at 9:58 am, the laboratory was unable to provide a record of patient test results reported from January 2020 through the date of inspection. 2. Interview with LD, at 10:30 am on 07/20/2022, confirmed that even though results were reported, the laboratory was not able to retrieve results because no record was kept. 3. According to CMS 116 submitted at the time of inspection, the annual volume was 3000.
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.

	This STANDARD is not met as evidenced by: Based on lack of pathology slides and interview with Laboratory Director (LD), the laboratory failed to retain histopathology microscopic examinations slides as required from 2012 through 2022. Findings Include: 1. On the day of survey 07/20/2022, during the interview with LD, it was stated that "the laboratory takes the slides to their other facility, located in Lancaster PA, after each day of patient testing for storage". 2. On the day of survey, 07/20/2022 at 10:15 am, the laboratory provided slides examined in 2022 but could not provide slides examined prior to 2022.. 3. The LD confirmed the findings above on 07/20/2022 at 10:30 am.