Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 10D2138281	**(X3) Date Survey Completed** 02/02/2024
Name of Provider or Supplier Premium Practice Solutions Llc	**Street Address, City, State** 5340 N Federal Hwy Suite 110, Lighthouse Point, 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 02/01/2024 to 02/02/2024 found the PREMIUM PRACTICE SOLUTIONS LLC clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
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 slide records review and interview, the laboratory failed to retain quality control slides for the required timeframe for three out of five patients reviewed from 03/01/2022 to 01/31/2024. Findings included: 1-Review of Test Menu listed on form CMS-116 signed by the current Laboratory Director on 01/29/2024, revealed that the laboratory performed the Histological interpretation for the following stains: Hematoxylin and Eosin (H&E); Immunohistochemical staining (IHC): Cluster of Differentiation 3 T cell Lymphocytic (CD3) and Helicobacter pylori (H. pylori); Special stains: Trichrome and Periodic Acid Schiff, polysaccharides (PAS). 2-Review of Technical Quality Assurance form and Slide Delivery log and slides for the following patients: Patient # 1 (P#1) (dated 04/18/2022) and P#2 (dated 08/29/2022), P#3 (dated 11/18/2022), P#4 (dated 02/20/2023) and P#5 (dated 03/03/2023) revealed the following: P#1: Patient had 5 slides with 3 H&E, 1 IHC H. pylori and 1 PAS stained slides and two control slides. The laboratory failed to retain the negative control for H. pylori and PAS. P#2: Patient had 19 stained slides: 7 H&E, 4 CD3, 1 H.

	pylori, 2 PAS, 3 Trichrome and 2 negative controls for IHC. The laboratory failed to retain the positive control for H. pylori and CD3. P#3: Patient had 2 H&E stained slides. P#4: Patient had 2 H&E stained slides. P#5: Patient sample had 9 stained slides: 3 H&E, 1 CD3, 1 H. pylori; 2 Trichrome stain slides and 2 negative IHC slides. The laboratory failed to retain the positive control for H. pylori and CD3 IHC. During an interview on 02/01/2024 at 10:30 AM, with laboratory consultant he confirmed that the laboratory failed to keep the slides listed above for the required timeframe.
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 lack of records and laboratory consultant interview, the laboratory failed to ensure the twice a year accuracy verification for histopathology testing for two out of two years reviewed. Findings included: - Review of Test Menu listed on form CMS-116 signed by current Laboratory Director on 01/29/2024, revealed that the laboratory performed the Histological interpretation for the following stains: Hematoxylin and Eosin (H&E); Immunohistochemical staining (IHC): Cluster of Differentiation 3 T cell Lymphocytic (CD3) and Helicobacter pylori (H. pylori); Special stains: Trichrome and Periodic Acid Schiff, polysaccharides (PAS). -Review of personnel records revealed that the Laboratory Director (LD), Clinical Consultant (CC), Technical Supervisor (TS), General Supervisor (GS) and Testing Person (TP) was the same person from 03/01/2022 to 01/22/2024. This LD retired and the new LD started on 01/26/2024. -Review of laboratory testing records revealed that the laboratory performed testing during the years 2022 and 2023. - The laboratory had no records that performed peer review on the slide interpretation for years 2022 and 2023. - During an interview on 02/01/2024 at 10:30 AM, the laboratory consultant confirmed that the laboratory failed to do twice a year accuracy verification histopathology during 2022 and 2023.