Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 39D2086652	**(X3) Date Survey Completed** 05/13/2021
Name of Provider or Supplier Pdp West Chester	**Street Address, City, State** 606 E Marshall St, Suite 107, West Chester, 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**
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 documentation and interview with the Histology Supervisor (HS), the laboratory failed to verify twice annually the accuracy of Mohs microscopic examinations performed in 2019. Findings include: 1. On the day of survey, 05/13 /2021, the laboratory could not provide documentation for verification of accuracy for Mohs microscopic examination twice annually in 2019. 2. The laboratory provided only one peer review performed in July 2019 3. The HS confirmed the findings above on 05/13/2021 at 10:30 a.m.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on record and policy review and interview with Histology Supervisor (HS), the laboratory failed to follow their written laboratory's Quality Assurance (QA) procedure for 2021. Findings include: 1. The laboratory's Quality Assurance (QA) procedure states:" the laboratory director must hold monthly staff meetings. Minutes should be taken and retained as documentation". 2. On the day of survey 05/13/2021,

	the laboratory could not provide QA minutes meeting records for the month of April 2021. 3. The HS confirmed the findings above on 05/13/2021 at 10:30 a.m.
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the Histology Manager (HM), the laboratory did not have the required records accessible during the course of the inspection on 05/13/2021. Findings Include: 1. On the day of survey 05/13/2021, the laboratory could not provide the following records upon request for Mohs Microscopic examinations: - Mohs Microscopic examinations slides from 12/07/2018 to 02/05/2021. - Quality assessment records from 12/07/2018 to 02/05/2021. - Quality control records from 12/07/2018 to 02/05/2021. - Mohs maps records from 12/07/2018 to 02/05/2021. - Final reports for Mohs Microscopic examinations from 12/07/2018 to 02/05/2021 2. The HM confirmed the findings above on 05/13/2021 at 10:30 a.m.