

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0195312	(X3) Date Survey Completed 07/19/2023
Name of Provider or Supplier Arthur K Balin Md Phd Pc Lab	Street Address, City, State 110 Chesley Drive, Media, 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
D6094	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of quality assurance (QA) documentation and interview with the Testing Personnel (TP) #2 (CMS 209), the laboratory director (LD) failed to perform QA to ensure the quality of services provided by the laboratory and to identify failures in quality from 05/25/2021 to 07/19/2023. Findings include: 1. On the date of the survey, 07/19/2023 at 12:10 PM, the laboratory could not provide documentation for the periodic QA evaluation performed to assess the laboratory's pre-analytical, analytical, and post-analytical processes from 05/25/2021 to 07/19/2023. 2. According to the laboratory's QA procedure manual, the laboratory should perform QA at least twice a year. 3. The laboratory performed 2,372 histopathology and dermatopathology examinations in 2022 (CMS-116 annual volume). 4. TP #2 confirmed the findings above on 07/19/2023 around at 12:30 PM. 5. Repeated Deficiency from inspection on 05/25/2023.</p>