Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2223876	(X3) Date Survey Completed 07/28/2021
Name of Provider or Supplier Hnl - Acl - Hecktown Oaks	**Street Address, City, State** 3780 Hecktown Road, Easton, 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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of laboratory policies and, interview with the Quality Safety / Risk Management / Process Excellence Director and the Regulatory / Accreditation Specialists #1, the laboratory failed to have all laboratory procedures signed and dated by the current laboratory director (LD) prior to patient testing on 07/01/2021. Findings include: 1. On the day of complaint investigation, 07/28/2021, a sample of the laboratory procedures, revealed the following procedures were not signed by the current laboratory director prior to the start of patient testing on 07/01/2021: - 3 of 3 Histopathology procedures. - 2 of 2 Cytology procedures. - 63 of 127 Laboratory procedures. 2. From 07/01/2021 to 07/28/2021 the laboratory performed 3,122 patient tests. 3. The Quality Safety / Risk Management / Process Excellence Director confirmed the findings above on 07/28/2021 around 3:00 pm.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by:

	Based on review of laboratory records and interview with the Quality Safety / Risk Management / Process Excellence Director and the Regulatory / Accreditation Specialist #1, the Laboratory Director failed to ensure that prior to testing patients specimen, all testing personnel (TP) were trained for each test performed onsite from 07/01/2021 to the date of complaint investigation. Findings include: 1. On the day of complaint investigation, 07/28/2021, the laboratory was unable to provide training records for each TP who performed patient testing at the Hecktown site from 07/01 /2021 to 07/28/2021. 2. From 07/01/2021 to 07/28/2021 the laboratory performed 3,122 patient tests. 3. The Quality Safety / Risk Management / Process Excellence Director confirmed the findings above on 07/28/2019 around 3:00 pm.