Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2225871	(X3) Date Survey Completed 04/13/2022
Name of Provider or Supplier Ahn Wexford Hospital	**Street Address, City, State** 12351 Perry Hwy, First Floor Laboratory, Wexford, 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
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Laboratory Manager (LM), the laboratory failed to include a positive and a negative control materials each day of patient testing for Potassium Hydroxide (KOH), Wet Mounts, and Fern microscopic examinations from 09/31/2021 to 04/13/2022. Findings include: 1. On the date of survey, 04/13/2022 at 01:30 pm, the laboratory could not provide documentation of quality control for KOH, Wet Mounts, and Fern microscopic examinations from 09/31 /2021 to 04/13/2022. 2. The following number of specimens were examined from 09 /31/2021 to 04/13/2022: - KOH: 106 - Wet Mount: 106 - Fern:106 3. The LM confirmed the findings above on 04/13/2022 at 05:30 pm.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: Based on review of immunohistochemistry quality control (QC) log records and interview with the Laboratory Manager (LM), the laboratory failed to document a positive and negative reactivity every day of patient testing for Immunohistochemical (IHC) stains performed from 09/30/2021 to 04/13/2022. Findings include: 1. On the day of survey 04/13/2022 at 03:30 pm., review of IHC Staining records revealed, IHC positive and negative controls were not documented from 09/30/2021 to 04/13/2022. 2. The LM confirmed the finding above on 04/13/2022 around 05:30 pm.