

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D1105840	(X3) Date Survey Completed 07/19/2021
Name of Provider or Supplier Premier Diagnostics	Street Address, City, State 1349 S Rochester Road Suite 210, Rochester Hills, MI	
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
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager (OM), the laboratory failed to ensure the Hematoxylin and Eosin (H & E) for 1 (#8) of 13 and the immunohistochemical stain, Warthin for 1 (#13) of 13 patient charts reviewed were documented for positive and negative reactivity each day of patient testing. Findings include: 1. A review of the laboratory's "H & E Quality Log" revealed the lack of documentation of the positive and negative reactivity for the H & E stain for 1 (#8) of 13 patient charts reviewed on 9/09/2020. 2. A record review of the special stains logs revealed the log was put into use in 4/2021. 3. A record review revealed for 1 (#13) of 13 patient charts reviewed a lack of documentation of the positive and negative reactivity for the Warthin stain for patient #13 report date on 7/07/2021. 4. A interview on 7/19/2021 at 11:15 AM and 11:30 AM, the OM confirmed a lack of documentation for the positive and negative reactivity for the H & E and immunohistochemical Warthin stain.</p>