

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0977014	(X3) Date Survey Completed 09/12/2018
Name of Provider or Supplier Robert J O'Brien Jr Md And Associates	Street Address, City, State 955 Main St Suite G6, Winchester, MA	
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
D0000	A CLIA recertification survey was conducted for the Robert J O'Brien Jr MD and Assoc laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
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, the laboratory failed to document all control procedures performed as evidenced by the following: A review of Mohs histopathology quality control records for calendar years 2017 and 2018 revealed no documentation of quality control for the differential hematoxylin and eosin (H&E) stain was being checked each day of Mohs slide examinations. One testing person and Mohs histotechnologist confirmed by interview on 9/12/18 at 9:25 AM that quality control of H&E staining was not being documented each day of Mohs slide examinations. The laboratory performs approximately 1594 Mohs slide examinations annually.</p>