

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D0977014	<b>(X3) Date Survey Completed</b>  06/15/2021
<b>Name of Provider or Supplier</b>  Robert J O'Brien Jr Md And Associates	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	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.
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the histotechnician on 6/15/21, the laboratory failed to verify at least twice annually procedures it performs that are not included in subpart I of this part as evidenced by the following: The surveyor reviewed the laboratory's procedure for twice annual peer slide review of Mohs cases on 6/15/21. The review revealed that laboratory's procedure for peer slide review of Mohs cases stated that five (5) cases would be twice annually reviewed by the other Mohs surgeon to verify the accuracy of the diagnoses. A review of calendar years 2019 and 2020 quality assessment records revealed that there was no documentation available to verify that the laboratory performed twice annual peer slide reviews for Dr. Thomas E. Rohrer's Mohs cases in calendar year 2020. The documented reviews were performed on 8/16/19, 10/22/19, and 11/3/2020. The histotechnician interviewed on 6/15/21 at 1:58 P.M. verified that the twice annual peer slide review for Dr. Thomas E. Rohrer's Mohs cases in calendar year 2020 was only performed once in 2020. .</p>
<b>D5805</b>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification,</p>

either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the histotechnician on 6/15/2021, the laboratory failed to indicate on the patient final test report the correct name of the laboratory where the test was performed as evidenced by the following: The surveyor reviewed twelve (12) patient final test reports between January 2019 and April 2021 in the Electronic Medical Record (EMR) Centricity. The review revealed: The laboratory failed to indicate the correct name of the laboratory location where the test was performed for twelve (12) out of twelve (12) patient final test reports. The name of the laboratory on the patient final test reports in the EMR Centricity was Dermatology Associates for Dr. Benjamin A. Solky's Mohs reports and "All" (no name) for Dr. Thomas E. Rohrer's Mohs reports. The laboratory's name on the CLIA certificate is Robert J O'Brien Jr MD and Assoc. The histotechnician confirmed on 6/15/2021 at 3:20 PM that the patient final test reports did not indicate the correct name of the laboratory where the test was performed. The laboratory performs 1744 Mohs cases annually.