

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 14D2156198	<b>(X3) Date Survey Completed</b> 03/13/2019
<b>Name of Provider or Supplier</b> Blessing Hospital Outpatient Dermatology	<b>Street Address, City, State</b> 1132 Broadway Street - Ste 200, Quincy, IL	
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>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the office manager (OM); the laboratory failed to have a procedure in place to evaluate the method accuracy of Mohs histopathology testing. Findings Include: 1. Review of laboratory's policy and procedure manual found the laboratory failed to have procedures in place to ensure the bi-annual method accuracy of Mohs histopathology testing. 2. On survey date 3-13-2019, at 1:00 pm, the OM confirmed no procedure was in place to ensure the bi-annual method accuracy of Mohs histopathology testing.</p>
<b>D5601</b>	<p><b>HISTOPATHOLOGY</b> 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 review of laboratory records and interview with the office manager (OM);</p>

the laboratory failed to document and perform Hematoxylin and Eosin (H&E) differential staining for 2 of 7 patient testing dates reviewed. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the policy, "Quality Assurance for Routine Stains", which stated: "1. A quality control slide will be run each day the lab operates. 2. The QC (quality control) slide will be for Hematoxylin and Eosin and/or Toliudine blue. Whichever is used in the lab. 3. The QC for the H&E will be of normal skin, have a crisp blue nuclei and light blue to purple counter stain." "The lab director will determine whether the stain is acceptable for the day. Each QC will be logged on the stain QC chart." 2. Review of patient testing for Mohs histopathology found for 2 of 7 patient testing dates reviewed the laboratory failed to have a corresponding H&E quality control slide. Date of Patient Testing 12-18-2018 12-19-2018 3. Review of the "Quality Control Staining" log found no documentation that a quality control slide was performed and determined to be acceptable for 12-18-2018 and 12-19-2018. 4. Review of patient testing logs found a total of 19 patients who were tested on 12-18-2018 and 12-19-2018 for Mohs histopathology. 5. On survey date 03-13-2019, at 1:00 pm, the OM confirmed no quality control slides were found and no quality control records were documented for differential staining on 12-18-2018 and 12-19-2018 when Mohs histopathology testing was performed.

**D5781**

**CORRECTIVE ACTIONS**

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
 Based on review of laboratory records and interview with the office manager (OM); the laboratory failed to perform corrective actions for out of range humidity readings for 9 of 10 dates when histopathology testing was performed. 1. The laboratory's 2018 and 2019 "Room Temperature" logs indicate humidity should be "60% >". 2. Review of the 2018 and 2019 "Room Temperature" logs identified that the humidity was less than the laboratory's established acceptability criteria for 9 of 10 histopathology testing dates. Testing Date Humidity Reading 12-18-2018 60% 12-19-2018 30% 12-20-2018 33% 01-07-2019 30% 01-21-2019 24% 02-04-2019 28% 02-05-2019 26% 02-07-2019 29% 03-11-2019 25% 03-12-2019 26% 3. On survey date 03-13-2019, at 1:00 pm, the OM confirmed no corrective actions were taken for out of range humidity readings for 9 of 10 dates when histopathology testing was performed.

**D5805**

**TEST REPORT**

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, 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 review of laboratory records and interview with the office manager (OM); the laboratory failed to include all the required components of a laboratory test report for 6 of 6 patient test reports reviewed. Findings Include: 1. Review of 6 of 6 patient test reports for Mohs histopathology found the laboratory failed to indicate the address of the laboratory and the test result for the Mohs histopathology procedure. Patient Identification Test Date P1 03-12-2019 P2 02-05-2019 P3 01-21-2019 P4 02-18-2019 P5 12-18-2018 P6 12-20-2018 2. On survey date 03-13-2019, at 1:00 pm, the OM confirmed the above findings.

**D6168**

TESTING PERSONNEL  
CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:

Based on review of laboratory records and interview the office manager (OM); the laboratory failed to ensure all employees met the qualification requirements of 493.1489 for high complexity testing. Findings Include: 1. 4 of 6 testing personnel (TP) listed on the CMS-209 failed to qualify for high complexity testing. See D6171.

**D6171**

TESTING PERSONNEL QUALIFICATIONS  
CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could

have qualified as a technologist under 493.1491 on or before February 28, 1992; (b) (4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6) (i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interviews with the office manager (OM); the laboratory failed to ensure 4 of 6 testing personnel were qualified for high complexity testing. Findings Include: 1. Review of educational documentation for 4 of 6 testing personnel (TP) identified on the CMS-209 failed to meet the minimum education requirements for high complexity testing. a. TP#2 - no qualifying educational documentation for high complexity pathology grossing b. TP#3 - no qualifying educational documentation for high complexity pathology grossing c. TP#4 - no qualifying educational documentation for high complexity pathology grossing d. TP#6 - no qualifying educational documentation for high complexity pathology grossing 2. On survey date 03-13-2019, at 1:00 pm, the above findings were confirmed by the OM.