

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0980104	(X3) Date Survey Completed 08/31/2022
Name of Provider or Supplier Dermatologists Of Southwest Ohio	Street Address, City, State 5720 Blazer Parkway, Dublin, OH	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review, and an interview with the Practice Manager, the laboratory failed to follow a written policy and procedure to assess competency of the Testing Personnel (TP) #8 as specified in the personnel requirements in subpart M. This deficient practice had the potential to affect all patients tested at this laboratory in the subspecialty of histopathology from 03/09/2022 to 08/31/2022. Findings Include: 1. A virtual review of the laboratory's CMS-209 Personnel Report form, approved and signed by the Lab Director on 08/30/2022, found eight individuals listed as TP. 2. A virtual review of the laboratory's "Competency Assessment Policy" found the following: "...3. During the employment with DGC/DOCS, a competency assessment will be performed: a. Initially b. 6 months c. yearly..." 3. A virtual review of the laboratory's Competency Assessment documentation, failed to find evidence of an initial competency assessment for TP #8. 4. An email with the Practice Manager, on 09/01/2022 at 10:40 AM, confirmed that the laboratory failed to perform an initial competency assessment for TP #8 after the hire date of 03/09/2022 and prior to patient testing.</p>
D6168	<p>TESTING PERSONNEL CFR(s): 493.1487</p> <p>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.</p>

This CONDITION is not met as evidenced by:

Based on record review and an email interview, the laboratory failed to ensure Testing Personnel (TP) #8 met the qualification requirements of 493.1489 for high complexity testing. This deficient practice had the potential to affect all patients tested in the subspecialty of histopathology from 03/09/2022 to 08/31/2022. Findings Include: 1. The laboratory failed to ensure TP #8 met the high complexity testing personnel qualification requirements. (Refer to 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 record review and an email interview, the laboratory failed to ensure Testing Personnel (TP) #8 met the appropriate educational requirements. This deficient practice had the potential to affect all patients tested under the subspecialty of histopathology from 03/09/2022 to 08/31/2022. Findings include: 1. Review of the CMS-209 Personnel Report Form found TP #8 listed as testing personnel under the subspecialty of histopathology. 2. Review of education documents failed to find the 60 semester equivalent credit hours to qualify as having an associates degree. 3. The Practice Manager confirmed via an email, sent 09/01/2022 at 10:40 AM, that the lab failed to ensure TP #8 met the educational requirements for high complexity testing.