

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2170608	(X3) Date Survey Completed 03/30/2021
Name of Provider or Supplier Dean Mcgee Eye Institute Pathology Services	Street Address, City, State 608 Stanton L Young Blvd, Oklahoma City, OK	
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	The initial survey was performed on 03/30/2021. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director at the conclusion of the survey.
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with technical supervisor #2, the laboratory failed to document the reactivity of the H&E (Hematoxylin and Eosin) stain each day of testing for 7 of 7 days. Findings include: (1) On 03/30/2021 at 09:00 am, technical supervisor #2 stated to the surveyor the laboratory performed microscopic interpretations of ophthalmic specimens using H & E stain; (2) The surveyor reviewed 7 patient records where patient slides, stained with H & E stain, had been microscopically reviewed. For 7 of 7 patients (test dates were 01/16/2020, 03/02/2020, 05/22/2020, 07/14/2020, 09/21/2020, 11/11/2020, and 02/26/2021), there was no evidence the reactivity of the stain had been observed for acceptability; (3) The surveyor reviewed the records with technical supervisor #2 and the laboratory director. Both stated on 03/30/2021 at 09:15, the reactivity of the stain had been observed during the microscopic interpretation, but had not been documented.</p>
D6171	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b)</p>

(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 a review of records and interview with the laboratory director and technical supervisor #2, the laboratory failed to ensure the person performing high complexity gross examinations (physical/description of tissue including color, weight, measurement and other characteristics of the tissue) in the absence of the technical supervisor were reviewed within 24 hours for 4 of 6 patients. Findings include: (1) On 03/30/2021 at 09:00 am, technical supervisor #2 stated to the surveyor testing person #1 performed gross examinations; (2) The surveyor then reviewed personnel education and training records. Testing person #1 qualified (493.1489 (b)(1)) to perform high complexity testing; (3) The surveyor reviewed patient records, which included grossing performed by testing person #1, from 03/02/2020 through 02/26/2021. There was no documented review by the technical supervisor within 24 hours for 4 of 6 patient records reviewed: (a) Record #DM20-0301 performed on 05/22/2020 (b) Record #DM20-0446 performed on 07/14/2020 (c) Record #DM20-0792 performed on 11/11/2020 (d) Record #DM21-000132 performed on 02/26/2021 (4) The surveyor asked technical supervisor #2 and the laboratory director if the technical supervisor documented a review of the gross examinations performed by testing person #1 within 24 hours. Both stated to the surveyor on 03/30/2021 at 09:15 am, the technical supervisor had not documented a review within 24 hours of the gross examination performed by testing person #1. Note: The Interpretive Guidelines at 493.1489(b)(7) state, "In the case of gross examinations, the technical supervisor may delegate to individuals qualified under 493.1489 the responsibility for the physical examination/description, including color, weight, measurement and other characteristics of the tissue; or other mechanical procedures for which a specific written protocol has been developed. The technical supervisor is ultimately responsible for the diagnosis related to the gross examination and must sign the examination report. The technical supervisor is not required to provide direct on-site supervision but is responsible for the accuracy of all test results reported. All physical examinations/descriptions of tissue including color, weight, measurement and other characteristics of the tissue; or other mechanical procedures performed in the absence of the technical supervisor by individuals qualified under 493.1489 should be reviewed within 24 hours by the technical supervisor."