

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0981930	(X3) Date Survey Completed 11/25/2024
Name of Provider or Supplier National Prion Disease Pathology	Street Address, City, State 2085 Adelbert Road, Room 419, Cleveland, 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
D0000	A revisit was conducted on 05/21/2025 for the National Prion Pathology laboratory (CLIA# 36D0981930), for all previous deficiencies cited on 11/25/2024. All deficiencies have been corrected and no new noncompliance was identified. The laboratory is in compliance with the Conditions of Participation at 42 CFR Part 493, Laboratory Requirements.
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> <p>This CONDITION is not met as evidenced by: Based on record review and an interview with General Supervisor (GS) #1, the laboratory failed to ensure Testing Personnel (TP) #10 met the qualification requirements of 493.1489 for high complexity testing. This deficient practice had the potential to affect two out of two patients tested in the subspecialty of Histopathology and the specialty of Chemistry from 03/01/2024 to 11/25/2024. Findings Include: 1. The laboratory failed to ensure TP #10 met the high complexity testing personnel qualification requirements. (Refer to D6171)</p>
D6171	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b)</p> <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</p>

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 interviews with the General Supervisor (GS), the laboratory failed to ensure Testing Personnel (TP) #10 met the qualification requirements of 493.1489 for high complexity test procedures performed in the subspecialty of Histopathology and the specialty of Chemistry. This deficient practice

had the potential to affect two out of two patient specimens tested by TP #10 when they began testing on 03/01/2024 through 11/25/2024. Findings Include: 1. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director (LD) on 11/18/2024, found 10 individuals listed and certified by the Laboratory Director to perform high complexity test procedures. 2. Review of education documentation provided on the date of the inspection found that TP #10 possessed a Doctor of Philosophy (PhD) degree obtained from a foreign university. Further review of TP #10's education documents failed to find a foreign equivalency evaluation of the PhD degree obtained from a foreign university, as required. 3. The surveyor requested the foreign equivalency documentation from GS #1 for TP #10. The GS #1 confirmed via email on 11/28/2024 at 6:18 AM that the laboratory did not have adequate documentation to show that TP #10 met the high complexity testing personnel requirements and was unable to produce the requested foreign equivalency documentation.