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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 36D0682180 | (X3) Date Survey Completed 01/21/2025 |
| Name of Provider or Supplier Firelands Regional Medical Center Laboratory | Street Address, City, State 1111 Hayes Avenue, Sandusky, 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 |
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| 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 Administrative Director (AD), the laboratory failed to establish and follow written policies and procedures to assess the competency of the General Supervisor (GS) based on the responsibilities of the position, at a frequency determined by the laboratory as specified in the personnel requirements in subpart M for the high complexity testing procedures performed in the specialties of Microbiology, Chemistry, Immunology and Hematology. This deficient practice affected four out of four individuals qualified to perform the duties of GS. This deficient practice had the potential to affect 1,231,129 out of 1,231,129 patients tested in the specialties of Microbiology, Immunology, Chemistry, Hematology and Immunohematology from 01/01/2024 to 01/21/2025. Findings Include: 1. Review of the laboratory's Form CMS-209, provided on the date of the inspection and approved by the Laboratory Director on 01/21/2025, found four individuals listed and qualified to function as a GS. 2. Review of the laboratory's policies and procedures, provided on the date of the inspection, failed to find a competency assessment policy and procedure for the four individuals qualified to function as the GS. 3. Review of the laboratory's competency assessment documentation failed to find competency assessments for the four individuals qualified to function as a GS based on the responsibilities of the position. 4. The AD confirmed the laboratory failed to establish a competency assessment policy and procedure for the GS. The AD also confirmed that the laboratory failed to document GS competency assessments based on the responsibilities of each position, at a frequency determined by the laboratory and was unable to provide the requested</p> |

documentation on the date of the inspection. The interview occurred on 01/21/2025 at 3:20 PM.

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:

Item I: Based on record review and an interview with the Administrative Director (AD), the laboratory failed to ensure Testing Personnel (TP) #13 met the qualification requirements of 493.1489 for high complexity testing. This deficient practice had the potential to affect 1,231,129 out of 1,231,129 patients tested in the specialties of Microbiology, Immunology, Chemistry, Hematology and Immunohematology from 01/01/2024 to 01/21/2025. Findings Include: 1. The laboratory failed to ensure TP #13 met the high complexity testing personnel qualification requirements. (Refer to D6171, Item I) Item II: Based on record review and an interview with the Administrative Director (AD), the laboratory failed to ensure Testing Personnel (TP) #20 met the qualification requirements of 493.1489 for high complexity testing. This deficient practice had the potential to affect 512,970 out of 512,970 patients tested in the subspecialty of Microbiology, Immunology, Chemistry, Hematology and Immunohematology from 08/15/2024, the day TP #20 began independent testing, to 01/21/2025. Findings Include: 1. The laboratory failed to ensure TP #20 met the high complexity testing personnel qualification requirements. (Refer to D6171, Item II)

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 (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) (A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted

occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (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. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Item I: Based on record review and an interview with the Administrative Director (AD), the laboratory failed to ensure Testing Personnel (TP) #13 met the qualification requirements of 493.1489 for high complexity testing. This deficient practice had the potential to affect 1,231,129 out of 1,231,129 patients tested in the specialties of Microbiology, Immunology, Chemistry, Hematology and Immunochemistry from 01/01/2024 to 01/21/2025. Findings Include: 1. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director (LD) on 01/21/2025, found 28 individuals listed and qualified by the Laboratory Director to perform high complexity testing procedures. 2. Review of education documentation provided on the date of the inspection found that TP #13 possessed a Bachelor of Science (BS) degree obtained from a foreign university. Further review of TP #13's education documents failed to find a foreign equivalency evaluation of the BS degree obtained from a foreign university, as required. 3. The surveyor requested the foreign equivalency documentation from the AD for TP #13. The AD confirmed that the laboratory did not have adequate documentation to show that TP #13 met the high complexity testing personnel requirements and was unable to produce the requested foreign equivalency documentation. The interview occurred on 01/21/2025 at 3:22 PM.

Item II: Based on record review and an interview with the Administrative Director (AD), the laboratory failed to ensure Testing Personnel (TP) #20 met the qualification requirements of 493.1489 for high complexity testing. This deficient practice had the potential to affect 512,970 out of 512,970 patients tested in the specialties of Microbiology, Immunology, Chemistry, Hematology and Immunochemistry from 08/15/2024, the day TP #20 began independent testing, to 01/21/2025. Findings Include: 1. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director (LD) on 01/21/2025, found 28 individuals listed and qualified by the Laboratory Director to perform high complexity testing procedures. 2. Review of education documentation provided on the date of the inspection found that TP #20 possessed a Medical Laboratory Technician (MLT) certification. Further review of TP #20's education documents failed to find evidence that TP #20 obtained the minimum education requirement to perform high complexity testing. 3. The surveyor requested a degree from the Administrative Director for TP #13. The AD confirmed that the laboratory did not have adequate documentation to show that TP #13 met the high complexity testing personnel requirements and was unable to produce the requested degree. The interview occurred on 01/21/2025 at 3:13 PM.