

| | | |
|--|--|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 52D0981226 | (X3) Date Survey Completed 10/31/2024 |
| Name of Provider or Supplier Progressive Community Health Centers, Inc | Street Address, City, State 3522 W Lisbon Ave, Milwaukee, WI | |
| 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 |
|---------------------------|---|
| D8100 | <p>INSPECTION REQUIREMENTS CFR(s): 493.1771</p> <p>Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of Clinical Laboratory Improvement Amendments (CLIA) Applications for Certification (CMS Form 116) submitted by the laboratory and the FDA (Food and Drug Administration) CLIA Medical Devices Database, and email correspondence with the Medical Operations Director, the laboratory did not limit testing to waived and provider performed testing as required for a PPM certificate at 493.19(c): Provider-performed microscopy (PPM) procedures. Findings include: 1. The laboratory performed testing outside the scope of their CLIA certificate by performing the AmniSure ROM (Rupture of [Fetal] Membranes) Test, a moderate complexity test, since March 2, 2022. See D8201.</p> |
| D8201 | <p>INSPECTION OF COW OR PPMP LABS CFR(s): 493.1775(b)</p> <p>(b) If necessary, CMS or a CMS agent may conduct an inspection of a laboratory issued a certificate of waiver or a certificate for provider-performed microscopy procedures at anytime during the laboratory's hours of operation to do the following: (b)(1) Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health. (b)(2) Evaluate a complaint from the public. (b)(3) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory. (b)(4) Collect information regarding the appropriateness of tests specified as waived tests or</p> |

provider-performed microscopy procedures.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (CMS Form 116) forms submitted by the laboratory in 2023 and 2024 and the FDA (Food and Drug Administration) CLIA Medical Devices Database, and email correspondence with the Medical Operations Director, the laboratory performed the AmniSure ROM (Rupture of [Fetal] Membranes) Test, a moderate complexity test, on nine patient samples since the laboratory started AmniSure ROM testing on March 2, 2022. The laboratory's performance of the AmniSure test during thirty-two of the last thirty-two months was outside the scope of the laboratory's Provider Performed Microscopy Procedures (PPM) certificate. Findings include: 1. Review of the FDA CLIA Medical Devices Database showed the FDA classified the AmniSure ROM (Rupture of [Fetal] Membranes) Test as a moderate complexity test. 2. Review of the CMS Form 116 submitted by the laboratory via email to the state agency on November 7, 2024, showed the laboratory applied for a PPM certificate with a public health multi-site exception. Review of the test procedure list in 'Section VI, Waived Testing' revealed the list included the AmniSure ROM test. The laboratory had not identified any testing in 'Section VIII, Non-Waived Testing'. The Laboratory Director (staff A) signed the CMS 116 form on November 6, 2024. 3. Review of the CMS Form 116 submitted via email by the laboratory to the Wisconsin State Agency on May 24, 2024, showed the laboratory did not include the AmniSure ROM test as a test performed in the laboratory. The laboratory had not identified any testing in 'Section VIII, Non-Waived Testing'. The laboratory director (Staff B) signed the CMS Form 116 on May 23, 2024. 4. Review of the CMS Form 116 submitted by the laboratory to the Wisconsin State Agency on October 25, 2023, showed the laboratory did not include the AmniSure ROM test as a test performed in the laboratory. The laboratory had not identified any testing in 'Section VIII, Non-Waived Testing'. The laboratory director (Staff C) signed the CMS Form 116 on October 25, 2023. 5. Interview with the Medical Operations Director by email on November 8, 2024, at 10:43 AM revealed the laboratory began testing with the AmniSure ROM test on March 2, 2022, and confirmed nine patient tests were resulted since testing began.