| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 15D2118084 | 02/13/2020 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Midwives Care | 2930 Mckinley, South Bend, IN | |

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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| **D1000** | CERTIFICATE OF WAIVER TESTS<br>CFR(s): 493.15(c)<br><br>Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others: (1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following: (i) Bilirubin; (ii) Glucose; (iii) Hemoglobin; (iv) Ketone; (v) Leukocytes; (vi) Nitrite; (vii) pH; (viii) Protein; (ix) Specific gravity; and (x) Urobilinogen. (2) Fecal occult blood; (3) Ovulation tests-visual color comparison tests for human luteinizing hormone; (4) Urine pregnancy tests - visual color comparison tests; (5) Erythrocyte sedimentation rate-non-automated; (6) Hemoglobin-copper sulfate-non-automated; (7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; (8) Spun microhematocrit; and (9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, document review, and interview, the laboratory failed to ensure one of two non-provider performed microscopy (PPM) tests ("Pregmate" urine pregnancy) performed were categorized by FDA (Food and Drug Administration) as waived. Findings included: 1. Review of "Enclosure I Test Methodology and Annual Test Volume Log," signed by the Laboratory Director on 2-13-2020, indicated the laboratory performed 25 waived urine pregnancy tests annually, using a "Pregmate" test kit. 2. On 2-13-2020 at 1:15 PM, an opened 100 count bag of "Pregmate," urine pregnancy tests was observed. 3. Review of package insert for the "Pregmate" urine pregnancy tests did not indicate the test was either a PPM or waived test. 4. Review of the Food and Drug Administration (FDA) online test categorization database indicated |

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| | the "Pregmate" urine pregnancy test was not listed as PPM or waived in the database. 5. In interview on 2-13-2020 at 1:30 PM, SP1, Laboratory Director, confirmed the laboratory used the "Pregmate" urine pregnancy test as a waived test. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on document review, lack of documentation, and interview, the laboratory failed to have a written procedure manual for two of two PPM (provider performed microscopy) tests performed (wet mount and fern testing). Findings included: 1. Review of "Enclosure I Test Methodology and Annual Test Volume Log" form, signed by the Laboratory Director on 2-13-2020, indicated the laboratory performed 100 wet mount tests and 30 fern test annually. 2. On 2-13-2020 at 1:15 PM, SP1 confirmed the laboratory performed 100 wet mount tests and 30 fern tests annually. On the same date at 1:50 PM, upon request for written procedures (including procedures for specimen labeling, step-by-step procedures, and result reporting) for wet mount and fern testing, SP1 indicated none were available for review. |