| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br>23D2054540 | (X3) Date Survey Completed<br>10/17/2020 |
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| **Name of Provider or Supplier**<br>Wayne Health - Canfield And Tolan Park | **Street Address, City, State**<br>50 E Canfield Ste 101-S, Detroit, MI | |

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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| **D2016** | SUCCESSFUL PARTICIPATION<br>CFR(s): 493.803(a)(b)(c)<br><br>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.<br><br>This CONDITION is not met as evidenced by:<br>. Based on record review of the CMS database and the College of American Pathologists (CAP) proficiency testing reports, it was determined the laboratory failed to successfully participate in a CMS-approved proficiency testing program for the subspecialty of syphilis serology. Findings include: A review of the CMS database and the CAP proficiency testing reports revealed the laboratory failed to achieve satisfactory performance for the subspecialty syphilis serology. Refer to D2067 and D2074. |
| **D2067** | SYPHILIS SEROLOGY |

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| | CFR(s): 493.835(b)<br><br>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.<br><br>This STANDARD is not met as evidenced by:<br>. Based on review of the CMS database the College American Pathologists (CAP) proficiency testing reports, the laboratory failed to participate in 2 (1st event 2020 and 2nd event 2020) of 2 testing events for the subspecialty syphilis serology, which is unsatisfactory performance resulting in a testing event score of 0%. Findings include: Unsatisfactory performance for 2 of 2 overall testing events for the failure to participate in the subspecialty syphilis serology constitutes unsuccessful performance. Syphilis Serology PT Events Score 1st event 2020 0% 2nd event 2020 0% |
| **D2074** | SYPHILIS SEROLOGY<br>CFR(s): 493.835(e)<br><br>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review of the CMS database and the College of American Pathologists (CAP) proficiency testing reports, the laboratory failed to achieve satisfactory performance for the subspecialty syphilis serology for 2 (1st and 2nd events in 2020) out of 2 consecutive testing events. Findings include: 1. A record review of the CMS database and CAP proficiency testing reports revealed unsatisfactory performance for 2 out of 2 consecutive testing events: Syphilis Serology PT Event Score 1st event 2020 0% 2nd event 2020 0% |