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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 23D0365804 | (X3) Date Survey Completed 11/01/2021 |
| Name of Provider or Supplier Forum Medical Clinics, Pc | Street Address, City, State 25625 Schoenherr Road, Warren, 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 |
|---------------------------|---|
| D2016 | <p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: . Based on review of the CMS database and the American Proficiency Institute (API) proficiency testing reports, it was determined the laboratory failed to successfully participate in a CMS approved proficiency testing program for the chemistry analyte: urea nitrogen (BUN). Findings include: Review of the CMS database and the API proficiency testing reports showed unsatisfactory performance for 2 of 3 proficiency testing events. Refer to 2096 *** Repeat Deficiency from 11/07/2018 survey***</p> |
| D2096 | <p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> |

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

. Based on review of the CMS database and the American Proficiency Institute (API) proficiency testing reports, the laboratory failed to achieve satisfactory performance for the chemistry analyte: urea nitrogen (BUN) in 2 of 3 consecutive testing events. Findings include: Unsatisfactory performance for 2 of 3 consecutive proficiency testing events constitutes unsuccessful performance for urea nitrogen (BUN). BUN) PT event Score 1st event 2021 40% 3rd event 2021 60% ***Repeat Deficiency from 11/07/2018 survey ***

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

. Based on review of the CMS database and the American Proficiency Institute (API) proficiency testing reports, the Laboratory Director failed to provide overall management and direction in accordance with 493.1407 of this subpart. Findings include: 1. The Laboratory Director failed to ensure the laboratory successfully participated in a proficiency testing program as required under Subpart H. Refer to D6016.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

. Based on record review of the CMS database and the American Proficiency Institute (API) proficiency testing reports, the Laboratory Director failed to ensure the laboratory successfully participated in a proficiency testing program as required under Subpart H, resulting in subsequent unsuccessful performance for 2 (1st and 3rd events of 2021) out of 3 consecutive testing events. Findings include: 1. A record review of the CMS database and API proficiency testing reports revealed subsequent unsatisfactory performance for 2 out of 3 consecutive testing events for the chemistry analyte urea nitrogen (BUN): BUN PT Event Score 1st event 2021 40% 3rd event

2021 60% 2. A record review of the CMS database revealed initial unsuccessful proficiency testing performance for the chemistry analyte urea nitrogen (BUN): BUN PT event Score 2nd event 2018 60% 3rd event 2018 0%