

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0034973	(X3) Date Survey Completed 01/21/2022
Name of Provider or Supplier Cameron Memorial Community Hospital	Street Address, City, State 416 E Maumee Street, Angola, 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
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 document review and interview, the laboratory failed to successfully participated in the American Proficiency Institute (API) proficiency testing (PT) program for compatibility testing. The laboratory had unsatisfactory overall PT event testing scores (less than 100%) for two out of three PT testing events in 2021 (Event 1, 2021 and Event 3, 2021) and 2019 (Event 1, 2019 and Event 3, 2019) (Refer to D2181).</p>
D2181	<p>COMPATIBILITY TESTING CFR(s): 493.863(e)</p>

Failure to achieve an overall testing event score of satisfactory for 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 document review and interview, the laboratory failed to achieve an overall satisfactory proficiency testing (PT) event score of 100% in compatibility testing for two out of three testing events in 2021 (Event 1, 2021 and Event 3, 2021), resulting in unsuccessful performance. This is a repeat deficiency, the laboratory failed to achieve an overall satisfactory proficiency testing (PT) event score of 100% in compatibility testing for two out of three testing events in 2019 (Event 1, 2019 and Event 3, 2019), resulting in unsuccessful performance. Findings included: 1. Review of email communication sent from SP1, technical supervisor, on 1/19/2022, indicated the laboratory received an 80% in compatibility for testing event 1, 2021 and testing event 3, 2021. 2. Review of the "Proficiency Testing Performance Evaluation" from the "American Proficiency Institute" (API) indicated the laboratory's overall PT score for compatibility testing was 80% for testing event 1, 2021 and testing event 3, 2021. 3. In interview on 1/21/2022 at 11:02 am, SP1, technical supervisor, confirmed the laboratory received an overall PT score of 80% for compatibility testing during testing event 1, 2021 and testing event 3, 2021. 4. This is a repeat deficiency, the laboratory failed to achieve an overall satisfactory proficiency testing (PT) event score of 100% in compatibility testing for two out of three testing events in 2019 (Event 1, 2019 and Event 3, 2019), resulting in unsuccessful performance.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on document review and interview, the laboratory director failed to ensure the laboratory successfully participated in the American Proficiency Institute (API) proficiency testing (PT) program for compatibility testing. The laboratory had unsatisfactory overall PT event testing scores (less than 100%) for two out of three PT testing events in 2021 (Event 1, 2021 and Event 3, 2021) and 2019 (Event 1, 2019 and Event 3, 2019). (Refer to D6089).

D6089

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:

Based on document review and interview, the laboratory director failed to ensure the laboratory achieved an overall satisfactory proficiency testing (PT) event score of 100% in compatibility testing for two out of three testing events in 2021 (Event 1,

2021 and Event 3, 2021), resulting in unsuccessful performance. This is a repeat deficiency, the laboratory failed to achieve an overall satisfactory proficiency testing (PT) event score of 100% in compatibility testing for two out of three testing events in 2019 (Event 1, 2019 and Event 3, 2019), resulting in unsuccessful performance. Findings included: 1. Review of email communication sent from SP1, technical supervisor, on 1/19/2022, indicated the laboratory received an 80% in compatibility for testing event 1, 2021 and testing event 3, 2021. 2. Review of the "Proficiency Testing Performance Evaluation" from the "American Proficiency Institute" (API) indicated the laboratory's overall PT score for compatibility testing was 80% for testing event 1, 2021 and testing event 3, 2021. 3. In interview on 1/21/2022 at 11:02 am, SP1, technical supervisor, confirmed the laboratory received an overall PT score of 80% for compatibility testing during testing event 1, 2021 and testing event 3, 2021. 4. This is a repeat deficiency, the laboratory failed to achieve an overall satisfactory proficiency testing (PT) event score of 100% in compatibility testing for two out of three testing events in 2019 (Event 1, 2019 and Event 3, 2019), resulting in unsuccessful performance.