

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D1105812	(X3) Date Survey Completed 08/17/2020
Name of Provider or Supplier Memphis Pathology Laboratory DbA	Street Address, City, State 1425 Nw Blue Parkway, Lees Summit, MO	
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 2019 and 2020 chemistry proficiency testing (PT) results reported to the CLIA database by the PT provider and phone interview with the laboratory director, the laboratory failed to successfully participate in PT. See tags D2096 unsatisfactory performance in two out of three consecutive testing events for the same analyte; D2097 failure to achieve an overall testing event score for chemistry of satisfactory performance for two of three events.</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 chemistry proficiency testing (PT) results for 2019, 2020 and phone interview with the laboratory director, the laboratory failed to achieve satisfactory performance for the total bilirubin analyte testing in two out of three consecutive PT events. Findings: 1. Review of the chemistry PT results for the third event of 2019 revealed the laboratory obtained an unsatisfactory score of 0 percent for the analyte, total bilirubin. 2. Review of the chemistry PT results for the second event of 2020 revealed the laboratory obtained an unsatisfactory score of 0 percent for total bilirubin. 3. Phone interview with the laboratory director on August 12, 2020 at 10:30 AM confirmed the laboratory failed to achieve satisfactory performance for total bilirubin testing in two out of three consecutive events for 2019, 2020.

D2097

ROUTINE CHEMISTRY

CFR(s): 493.841(g)

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.

This STANDARD is not met as evidenced by:

Based on review of chemistry proficiency testing (PT) results for 2019, 2020 and phone interview with the laboratory director, the laboratory failed to achieve satisfactory performance for the specialty of chemistry in two out of three consecutive PT events. Findings: 1. Review of the chemistry PT results for the third event of 2019 revealed the laboratory obtained an unsatisfactory score of 0 percent for the specialty of chemistry. 2. Review of the chemistry PT results for the second event of 2020 revealed the laboratory obtained an unsatisfactory score of 0 percent for the specialty of chemistry. 3. Phone interview with the laboratory director on August 12, 2020 at 10:30 AM confirmed the laboratory failed to achieve satisfactory performance for the specialty of chemistry in two out of three consecutive events for 2019, 2020.