

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0315529	(X3) Date Survey Completed 05/12/2021
Name of Provider or Supplier Children's Clinic Pa Of West Tennessee, The	Street Address, City, State 264 Coatsland Dr, Jackson, TN	
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: The laboratory failed to maintain satisfactory proficiency testing (PT) performance for the specialty of chemistry and the bilirubin analyte for 2020 event two and 2021 event one, resulting in the first unsuccessful PT performance for the chemistry specialty and the bilirubin analyte. (Refer to D2096 and D2097)</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two</p>

consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a desk review of the Centers for Medicare and Medicaid Services Casper report 155 (CMS 155) and the laboratory's proficiency testing (PT) records, the laboratory failed to maintain satisfactory performance for the bilirubin analyte in two out of three PT events, resulting in the first unsuccessful PT occurrence for the bilirubin analyte. The findings include: 1. Review of the CMS 155 report revealed the following for the bilirubin analyte: 2020 event two scored as 0% 2021 event one scored as 20% 2. Review of the laboratory's proficiency testing records for 2020 event two revealed the bilirubin analyte was scored as 0% for "Results for this kit were not received." 3. Review of the laboratory's proficiency testing records for 2021 event one revealed sample numbers NB-01, NB-02, NB-04 and NB-05 scored as unacceptable, resulting in an overall score of 20% for the bilirubin analyte and the first unsuccessful PT occurrence for the bilirubin analyte.

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 a desk review of the Centers for Medicare and Medicaid Services Casper report 155 (CMS 155) and the laboratory's proficiency testing (PT) records, the laboratory failed to maintain satisfactory performance for the chemistry specialty in two out of three PT events, resulting in the first unsuccessful PT occurrence for the chemistry specialty. The findings include: 1. Review of the CMS 155 report revealed the following for the chemistry specialty: 2020 event two scored as 0% 2021 event one scored as 20% 2. Review of the laboratory's proficiency testing records for 2020 event two revealed the chemistry specialty was scored as 0% for "Results for this kit were not received." 3. Review of the laboratory's proficiency testing records for 2021 event one revealed the specialty of chemistry was scored as 20%, resulting the first unsuccessful PT occurrence for the chemistry specialty.