

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0315681	(X3) Date Survey Completed 06/07/2024
Name of Provider or Supplier Lexington Hospital Corporation	Street Address, City, State 200 West Church St, Lexington, 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: Based on a review of the Casper Report 155 (CMS 155) and the laboratory's American Proficiency Institute (API) proficiency testing (PT) evaluations reports, and staff interview, the laboratory failed to maintain satisfactory performance for the Rhesus factor (Rh) analyte and the immunohematology ABO/Rh subspecialty for two consecutive PT events resulting in unsuccessful PT performance. (Refer to D2162 and D2163).</p>
D2162	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(f)</p>

Failure to achieve satisfactory performance for the same analyte 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 a desk review of the Centers for Medicare and Medicaid Services Casper Report 155 (CMS 155) and the laboratory's American Proficiency Institute (API) proficiency testing (PT) performance evaluation reports, and staff interview, the laboratory failed to maintain satisfactory performance for the Rh analyte in two consecutive events resulting in unsuccessful PT performance. The findings include: 1. A review of the CMS 155 revealed unsatisfactory PT scores of 80 percent (%) for the Rh analyte for 2023 event three and 2024 event one. 2. A review of the laboratory's API performance evaluation reports revealed scores of 80% for 2023 event three and 2024 event one for the Rh analyte. 3. A phone interview on 06/12/2024 at 12:45 pm with the laboratory supervisor confirmed the survey findings.

D2163

ABO GROUP AND D(RHO) TYPING
CFR(s): 493.859(g)

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 review of the Casper Report 155 (CMS 155) and the laboratory's American Proficiency Institute (API) proficiency testing (PT) evaluations reports, and staff interview, the laboratory failed to maintain a satisfactory overall testing event score for two consecutive testing events for the immunohematology ABO/Rh subspecialty resulting in unsuccessful PT performance. The findings include: 1. A review of the CMS 155 revealed unsatisfactory scores of 90% for the ABO/Rh subspecialty for 2023 event three and 2024 event one. 2. A review of the laboratory's API PT performance evaluation reports revealed scores of 80% for the Rh analyte for 2023 event three and 2024 event one. This resulted in an overall unsatisfactory score of 90% for the ABO/Rh subspecialty for both events. 3. A phone interview on 06/12/2024 at 12:45 pm with the general supervisor confirmed the survey findings.