

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D0456115	(X3) Date Survey Completed 05/25/2022
Name of Provider or Supplier Harlan County Health System	Street Address, City, State 717 North Brown Street, Alma, NE	
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
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's 2021 and 2022 American Proficiency Institute (API) proficiency testing documentation, result logs, quality control logs, and interview with with the laboratory manager revealed the laboratory failed to perform proficiency testing in the same manner as it tests patient specimens for blood bank proficiency testing in 2022. Findings are: 1. Surveyor review of blood bank result logs and quality control logs from 1/2/2021 - 5/20/2022 for proficiency testing from 2021 event 1, 2021 event 2, 2021 event 3, and 2022 event 1 revealed the laboratory failed to perform quality control on 3/29/2022, when testing for 2022 event 1 was performed. 2. Interview with the laboratory manager on 5/25/2022 at 10:33 AM confirmed the laboratory failed to perform quality control on 3/29/2022.</p>
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</p>

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.

This CONDITION is not met as evidenced by:
Based on surveyor review of the laboratory's 2021 and 2022 American Proficiency Institute (API) proficiency testing (PT) records and interview with the laboratory manager on date of survey, 5/25/2022, it was determined the laboratory failed to successfully participate in proficiency testing for the analyte ABO/D(Rho). Refer to D2163.

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 surveyor review of the laboratory's 2021 and 2022 American Proficiency Institute (API) proficiency testing (PT) records and interview with the laboratory manager on date of survey, 5/25/2022, the laboratory failed to achieve successful performance for the analyte ABO/D(Rho), in two out of three testing events. Findings are: 1. 2021 Event 3, score 90% 2. 2022 Event 1, score 90% 3. Interview with the laboratory manager on 5/25/2022 at 10:33 AM confirmed the laboratory was unsuccessful in two out of three PT testing events.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:
Based on surveyor review of the CMS 209, competency evaluations for 2021, and an interview with general supervisor, the laboratory failed to perform competency evaluations on one out of three high complexity testing personnel for. Findings are: 1.

The CMS 209 form completed by the laboratory revealed three high complexity testing personnel performing patient testing. 2. Review of competency evaluations for 2021 revealed one high complexity testing personnel had no annual competencies performed for 2021. Testing personnel labeled as TP #1 on the CMS 209 form had no competencies performed for 2019. 3. Interview with the general supervisor at 1:25 PM on 5/25/2022, confirmed the competency evaluations for one high complexity testing personnel could not be presented at time of survey.