

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D1080092	(X3) Date Survey Completed 03/23/2022
Name of Provider or Supplier Hancock Regional Surgery Center, Llc	Street Address, City, State 1 Memorial Square, Suite 1000, Greenfield, 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 participate in the American Proficiency Institute (API) proficiency testing (PT) program in 2022 and College of American Proficiency (CAP)/Excel proficiency testing (PT) program in 2021 for endocrinology and human chorionic gonadotropin (HCG). The laboratory had unsatisfactory overall PT event testing scores (less than 80%) for two in a row PT testing events in 2021 (Event 3, 2021) and 2022 (Event 1, 2022). (Refer to D2099 and D2100).</p>
D2099	ENDOCRINOLOGY

CFR(s): 493.843(b)

Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:

Based on document review and interview, the laboratory failed to attain a score of 80% in the American Proficiency Institute (API) proficiency testing (PT) event 1 in 2022 for one of three sub-specialties performed (endocrinology) and one of one test performed in this sub-specialty (human chorionic gonadotropin (HCG)). Findings included: 1. Review of the "Proficiency Testing Performance Evaluation" from the "American Proficiency Institute" (API) indicated the laboratory's overall PT score for the sub-specialty of endocrinology and HCG testing was 60% for testing event 1, 2022. 2. Review of email communication sent from SP1, Nurse Manager, on 3/23/2022 at 2:32 pm, confirmed the laboratory received a 60% in the sub-specialty of endocrinology and HCG testing for event 1, 2022. This testing was completed with API.

D2100

ENDOCRINOLOGY

CFR(s): 493.843(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

Based on document review and interview, the laboratory failed to participate in the College of American Proficiency (CAP)/Excel proficiency testing (PT) program for event 3 in 2021 for one of three sub-specialties performed (endocrinology) and one of one test performed in this sub-specialty (human chorionic gonadotropin (HCG)) resulting in a score of 0 for the testing event. Findings included: 1. Review of the "Proficiency Testing Performance Evaluation" from CAP/Excel indicated the laboratory's overall PT score for the sub-specialty of endocrinology and HCG testing was 0% for testing event 3, 2021. 2. Review of email communication sent from SP1, Nurse Manager, on 3/23/2022 at 2:32 pm, confirmed the laboratory received an 0% in the sub-specialty of endocrinology and HCG testing for testing event 3, 2021 due to missing the event.