

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  06D0513186	<b>(X3) Date Survey Completed</b>  07/24/2023
<b>Name of Provider or Supplier</b>  Adventhealth Lab	<b>Street Address, City, State</b>  2525 South Downing St, Denver, CO	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An unannounced complaint survey was conducted at Centura Porter Adventist Hospital laboratory, located at 2525 S Downing Street, Denver, CO 80210, on July 24, 2023 at approximately 2:30 PM.
<b>D5301</b>	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on an onsite records review and an interview with the laboratory manager on Monday, July 24, 2023, the laboratory failed to ensure that the laboratory staff had a written or electronic test requests from an authorized person before performing Clostridium difficile (C. diff) testing on July 17, 2023, for four out of four patients stool specimens brought in from an outside laboratory. Findings include: 1. A review of laboratory records on July 24, 2023, revealed the laboratory did not have a written or electronic test request from an outside laboratory requesting C. diff testing on four out of four patients on July 17, 2023. 2. An interview with the outside laboratory manager on July 20, 2023, at approximately 12:15 PM, confirmed that a person from the outside laboratory took the four samples without orders or test requisition to the Centura Health-Porter laboratory for testing. The patient test results were then reported from the outside laboratory as if the specimens were tested there. 3. An interview with the laboratory manager on July 24, 2023, at approximately 2:45 PM, confirmed that the laboratory staff did not have written or electronic test requests to perform C. diff testing on four out of four patients from an outside laboratory on July 17, 2023. The laboratory manager also confirmed that the laboratory does not accept samples for C. diff testing from outside laboratories.</p>
<b>D5787</b>	TEST RECORDS

CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on an onsite records review and an interview with the laboratory manager on Monday, July 24, 2023, the laboratory failed to maintain testing records for four out of four specimens from an outside laboratory for Clostridium difficile (C. diff) testing on July 17, 2023, which included the identification of the specimen, the date and time the specimens were received in the laboratory, the records and dates of all specimen testing, and the identity of the personnel who performed the test. Findings include: 1. A review of records on July 24, 2023, revealed that the Centura Health-Porter laboratory did not maintain testing records for four out of four specimens brought in from an outside laboratory for C. diff testing on July 17, 2023. The laboratory failed to include the identification of the specimen, the date and time the specimen was received in the laboratory, the test records and dates of all specimen testing, and the identity of the personnel who performed the test. 2. A review of Centura Health-Porter's C. diff worksheets on July 24, 2023, revealed the laboratory failed to produce testing records for the four stool C. diff tests performed on July 17, 2023. 3. An observation on July 20, 2023, at approximately, 12:00 PM, revealed an outside laboratory had a copy of the Centura Health-Porter's C. diff worksheet for four patient specimens tested on July 17, 2023. 4. Based on an interview with the laboratory manager on Monday, July 24, 2023, at approximately 2:45 PM, it was confirmed that the laboratory did not maintain records of four specimens brought into the Centura Health-Porter laboratory from an outside laboratory for C. diff testing on July 17, 2023.

**D5803**

**TEST REPORT**

CFR(s): 493.1291(b)

Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.

This STANDARD is not met as evidenced by:

Based on an onsite records review and an interview with the laboratory manager on Monday, July 24, 2023, the laboratory failed to maintain four out of four patient test reports for Clostridium difficile (C. diff) testing performed on July 17, 2023. Findings include: 1. A review of records on July 24, 2023, revealed that the laboratory did not maintain four out of four patient test reports for C. diff testing that were brought into Centura Health-Porter from an outside laboratory. 2. An interview with the laboratory manager on July 24, 2023, at approximately 2:45 PM, confirmed that that laboratory did not have C. diff test reports for the four patient specimens that were tested at Centura Health-Porter that were brought into from an outside laboratory.