

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 43D0041649	<b>(X3) Date Survey Completed</b> 01/10/2023
<b>Name of Provider or Supplier</b> Philip Health Services Inc	<b>Street Address, City, State</b> 503 West Pine Street, Philip, SD	
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>	A recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 1/10/23. Philip Health Services Inc laboratory was found not in compliance with the following requirement(s): D2003, D6047, D6048, and D6053.
<b>D2003</b>	<p>ENROLLMENT CFR(s): 493.801(a)(2)(ii)</p> <p>For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1)</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to verify the accuracy of the c-reactive protein (CRP) test method for 24 of 24 months reviewed (1/1/21 through 12/31/22). This verification would have ensured the accuracy of patient CRP specimens reported during this time. Findings include: 1. Review on 1/10/23 of the laboratory's proficiency testing (PT) records revealed: *The laboratory subscribed to the American Proficiency Institute (API) for their PT program. *There was no record CRP had been included in this subscription. *Documentation of any alternative accuracy verification testing was requested on 1/10/23 at 11:40 a.m. *Laboratory manager A was unable to provide the requested documentation. Review on 1/10/23 of the Laboratory Proficiency Testing policy, last revised 7/16/21, revealed: "The facility subscribes to proficiency testing programs that have received HHS [United States Department of Health and Human Services] approval for all non-waived tests that the facility performs." Review of the laboratory test count form revealed 764 patient CRP specimens had been reported in 2022 without verification of the test method's accuracy. Interview on 1/10/23 at 11:40 a.m. with laboratory manager A revealed:</p>

\*He confirmed the CRP test method had not been included in the laboratory's PT program. \*He confirmed the laboratory had not verified the accuracy of the CRP test method by an alternative testing method.

**D6047**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(i)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

This STANDARD is not met as evidenced by:

Based on record review and interview, the technical consultant failed to ensure employees had received a competency assessment that included direct observation of routine patient testing to ensure accurate test performance by one of two laboratory personnel (B) reviewed for the patient testing he had performed under the laboratory's certificate. Findings include: 1. Review on 1/10/23 of laboratory personnel B's competency assessment revealed: \*He had started working in the laboratory on 4/18/22. \*His six-month competency assessment had been completed and signed by laboratory manager A on 10/24/22. \*His competency assessment lacked documentation of the direct observation of patient testing for the areas of bacteriology, virology, urinalysis and clinical microscopy. Review on 1/10/23 of the Laboratory Employee Competency policy, last revised 6/21/21, revealed, "Records utilized for the evaluation of employee competency shall include all of the following elements for all non-waived test systems... Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing." Interview on 1/10/23 at 11:40 a.m. with laboratory manager A revealed: \*He confirmed there had been no documentation of direct observation of patient testing in the areas of bacteriology, virology, urinalysis and clinical microscopy. \*He had not been aware direct observation of patient testing had not been documented for all testing areas included on the competency assessment.

**D6048**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(ii)

The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results.

This STANDARD is not met as evidenced by:

Based on record review and interview, the technical consultant failed to ensure employees had received a competency assessment that included monitoring the recording and reporting of patient test results by one of two laboratory personnel (B) reviewed for the patient testing he had performed under the laboratory's certificate. This review would have included the verification of the accuracy of manually entered patient test results. Findings include: 1. Review on 1/10/23 of laboratory personnel B's competency assessment revealed: \*He had started working in the laboratory on 4/18/22. \*His six-month competency assessment had been completed and signed by laboratory manager A on 10/24/22. \*His competency assessment lacked documentation of the monitoring, recording of information, and reporting of examination results in the areas of hematology and coagulation. Review on 1/10/23 of

the Laboratory Employee Competency policy, last revised 6/21/21, revealed, "Records utilized for the evaluation of employee competency shall include all of the following elements for all non-waived test systems... Monitoring the recording and reporting of test results including, as applicable, reporting critical results." Interview on 1/10/23 at 11:40 a.m. with laboratory manager A revealed: \*He confirmed there had been no documentation of monitoring the recording and reporting of patient test results in the areas of hematology and coagulation. \*He had not been aware monitoring the recording and reporting of patient test results had not been documented for all testing areas included on the competency assessment.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:  
Based on record review and interview, the technical consultant failed to ensure one of six newly hired laboratory personnel (laboratory manager A) had received two competency evaluations during his first year of patient testing for the test methods he had been performing under the laboratory's certificate. Findings include: 1. Review on 1/10/23 of the employee competency assessments for laboratory manager A revealed: \*He had started working in the laboratory on 4/29/21. \*There was documentation of initial training. \*A six-month competency assessment had been completed by the laboratory director on 11/29/21. \*An annual competency assessment had been completed by the laboratory director on 11/29/22. \*No records of additional competency evaluations were available for review. Review on 1/10/23 of the Laboratory Employee Competency policy, last revised 6/21/21, revealed: \*"New employees will have an initial competency assessment. They must be deemed competent on a test system/procedure before they perform independent testing on patient specimens." \*"During the first year of an individual's duties, competency will be assessed at 6 months after joining date." \*"After an individual has performed his /her duties for one year, competency will be assessed at least annually." Interview on 1 /10/23 at 11:40 a.m. with laboratory manager A revealed: \*He confirmed the laboratory director had completed only two competency assessments since his date of hire. \*He thought his training documentation qualified as an initial competency assessment.