

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0681956	(X3) Date Survey Completed 08/29/2019
Name of Provider or Supplier Horizon Health Mission	Street Address, City, State 161 S Main, Mission, SD	
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
D0000	A recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 8/29/19. The Mission Community Health Center laboratory was found not in compliance with the following requirements: D6028 and D6053.
D6028	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;</p> <p>This STANDARD is not met as evidenced by: Based on review of employee files, the CMS 209 Laboratory Personnel Report Form, and interview with laboratory staff A, the laboratory director failed to ensure competency evaluations for two of nine laboratory staff (B and C) were completed by authorized personnel (their credentials had not been reviewed to determine if they were qualified to serve as technical consultants) for the nonwaived test methods they had been performing under the laboratory's certificate. Findings include: 1. Review of employees' files for laboratory staff B and C revealed laboratory staff B and C had competency evaluations performed on 10/2/18 by laboratory staff A and D. The laboratory director had signed the competency evaluation. There was no indication the laboratory director was involved in the competency assessment process nor had he dated the evaluations. Review of the the CMS 209 Laboratory Personnel Report Form signed by the laboratory director on 7/16/19 revealed the laboratory director was also</p>

serving as the technical consultant. Laboratory staff A and D were listed only as testing personnel and not listed as technical consultants. Interview on 8/29/19 at 10:40 a.m. with laboratory staff A revealed neither she nor laboratory staff D had received written authorization from the laboratory director to perform employee competencies. The laboratory director was at the facility approximately every two weeks.

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 review of employee files, the Laboratory Testing Personnel Performance Review Policy, the December 2018 quarterly Quality Assurance (QA) form, and interview with the laboratory staff A, the laboratory director, also serving as the the technical consultant, failed to ensure: *One of one newly hired staff (B) had received two competency evaluations during her first year of patient testing for the test methods she had been performing under the laboratory's certificate. *One of nine staff (E) had received competency evaluations on an annual basis for the test methods she had been performing under the laboratory's certificate. Findings include: 1. Review of the employee files for laboratory staff B revealed: *She had a completed and signed orientation/training checklist dated 12/4/17. *A competency assessment had been completed on 10/2/18. *No records of additional competency evaluations were available. 2. Review of the employee files for laboratory staff E revealed no record of competency evaluation in 2018 or to date in 2019. Laboratory staff E's last competency evaluation had been dated 9/21/17. Review of the facility's Laboratory Testing Personnel Performance Review Policy last revised on 1/3/08, revealed: "In the first year laboratory testing personnel performance review will be done twice for a new employee. From there, this review will be done for each employee once a year." Review of the December 2018 quarterly QA form completed by laboratory personnel A on 12/10/18 and signed by the laboratory director 1/15/19 revealed laboratory personnel competency evaluations to be acceptable. Interview on 8/29/19 at 10:40 a. m. with laboratory staff A revealed no competency evaluations had been performed for laboratory staff E in 2018 or to date in 2019. She stated laboratory staff E rarely did laboratory work.