

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D0468429	<b>(X3) Date Survey Completed</b>  03/09/2021
<b>Name of Provider or Supplier</b>  Mercy Clinic Berryville	<b>Street Address, City, State</b>  207 Carter Street, Berryville, AR	
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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Through review of the CMS 209 form, personnel records and confirmed by interview it was determined that the competency of the testing personnel , identified as number two on the CMS 209 form, was not assessed on an annual basis and the competency of the same testing personnel was not assessed utilizing the required elements for determining competency. Findings follow: 1. The competency of the testing personnel, identified as number two on the CMS 209 form, was not evaluated on an annual basis. A) Review of personnel files revealed that documentation of the annual evaluation of the competency of the testing personnel, identified as number two on the CMS 209 form, was dated 3/13/18, 9/3/19 and 3/2/21 which represented a gap of 18 months between 3/13/18 and 9/3/19 and a gap of 17 months between 9/3/19 and 3/2/21.. B) In an interview on 3/9/21 at 02:00 PM, the technical consultant, identified as number three on the CMS 209 form, confirmed that the competency of the testing personnel was not performed on an annual basis.. 2. The competency of the testing personnel, identified as number two on the CMS 209 form was not evaluated utilizing the required elements for assessing testing personnel competency. A) Review of personnel files revealed documentation of annual competency evaluations for the testing personnel, identified as number two on the CMS 209 form, dated 9/3/19 and 3/2/21 were titled "Performance Evaluation of General Supervisor" and did not address performance of testing and did not include documentation that the required elements, i. e. direct observation of test performance, monitoring the recording and reporting of test results, review of records, observation of the performance of instrument maintenance, assessment of problem solving skills, and assessment of performance in</p>

testing blind sample material, were utilized in assessing testing personnel competency B) In an interview of 3/9/21 at 02:00 PM, the laboratory staff member, identified as number three on the CMS 209 form, confirmed that the competency evaluations identified above lacked documentation of the required elements of assessing testing personnel competency.

**D6032**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
. Through a review of laboratory personnel files, lack of documentation, and interviews with staff, it was determined the laboratory director failed to specify, in writing, which examinations and procedures each individual is authorized to perform and whether supervision is required. As evidenced by: A) Personnel records for six of six testing personnel (identified as numbers two and four through six on the form CMS-209) failed to include the director's written authorization to perform moderate complexity testing. B. In an interview at 02:00 PM, on 03/09/21, laboratory staff member, identified as number three on the CMS 209 form, confirmed there were no written authorizations from the current laboratory director identifying the tests that each individual is authorized to perform.