

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  27D0410237	<b>(X3) Date Survey Completed</b>  05/01/2024
<b>Name of Provider or Supplier</b>  Logan Health - Chester	<b>Street Address, City, State</b>  315 West Madison Ave, Chester, MT	
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>D6029</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(11)</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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on a record review of the CMS-209 Laboratory Personnel Report form, testing personnel records, laboratory policies, and an interview with technical supervisor (TS) #1, the laboratory director failed to ensure one out of three testing personnel had the minimal education requirements to perform moderate complexity testing from November 22, 2022, to May 1, 2024. Findings: 1. A review of the CMS-209 Laboratory Personnel Report form listed testing personnel (TP) #3 as moderate complexity, and a review of their personnel records contained competency assessments authorizing them to perform moderate complexity testing from November 22, 2022, to May 1, 2024. 2. A review of the "Lab Prep Technician" job description revealed TP #3 failed to have the minimal educational requirement as stated, "post high school education". 3. An interview with TS #1 on May 1, 2024, at 4:05 PM confirmed the laboratory director failed to ensure TP #3 had the minimal educational requirements to perform moderate complexity testing from November 22, 2022, to May 1, 2024.</p>
<b>D6063</b>	<p><b>LABORATORY TESTING PERSONNEL</b> CFR(s): 493.1421</p>

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on a review of testing personnel records, policies and interview with technical supervisor (TS) #1, the laboratory failed to ensure that one out of the three testing personnel listed on the CMS-209 Personnel Report Form had the appropriate educational background and applicable state licensure prior to performing moderate complexity testing. (See D6064 and 6065)

**D6064**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1423(a)

Each individual performing moderate complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

This STANDARD is not met as evidenced by:

Based on a record review of testing personnel files and an interview with technical supervisor (TS) #1, the laboratory failed to ensure one out of three testing personnel (TP) had an applicable state license to perform moderate complexity testing on human specimens from November 22, 2022, to May 1, 2024. Findings: 1. A review of TP #3 personnel records lacked an applicable Montana licensure to perform laboratory testing on human specimens. 2. An interview with TS #1 on May 1, 2024, at 10:30 AM confirmed TP #3 did not have an applicable Montana licensure to perform moderate-level testing on human specimens from November 22, 2022, to May 1, 2024.

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on a review of personnel files, the CMS-209 Laboratory Personnel Report (CLIA) form, and an interview with technical supervisor (TS) #1, the laboratory failed to ensure one out of three testing personnel had the appropriate educational background prior to performing moderate complexity testing from November 22, 2022, to May 1, 2024. Findings: 1. A review of TP #3 personnel records failed to have

a high school degree or equivalent prior to performing moderate complexity testing as authorized by their initial (11/22/2022), six-month (6/23/3023), and annual (11/20/2023) competency assessments from November 22, 2022, to May 1, 2024. 2. An interview with TS #1 on May 1, 2024, at 10:35 AM, confirmed TP #3 was classified as a lab prep technician and failed to have a high school degree or equivalent prior to performing moderate complexity testing from November 22, 2022, to May 1, 2024.