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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 38D0624280 | (X3) Date Survey Completed 11/21/2024 |
| Name of Provider or Supplier Kaiser Interstate Medical Office Lab | Street Address, City, State 3500 N Interstate Ave, Portland, OR | |
| 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 |
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| D6063 | <p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the CMS 209 form, testing personnel (TP) educational and competency records and interview with the Point of Care (PoC) Coordinator, the laboratory failed to ensure all TP in the PoC area performing moderate complexity testing had diplomas on file and competencies assigned were completed. Findings include: 1. See D6065, D6066</p> |
| D6065 | <p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(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</p> |

This STANDARD is not met as evidenced by:
Based on review of the personnel documents submitted for my review during survey and interview with the Point of Care (PoC) supervisor, the laboratory failed to ensure that all testing personnel (TP) performing whole blood Human Chorionic Gonadotropin (HCG) assays for pregnancy with the Adexus, had educational documents on site for review during survey. Findings include: 1. Upon review of TP records for personnel performing moderate complexity pregnancy testing in the PoC area since last survey 11/28/2022, and listed on the current CMS 209 form, four (4) new TP did not have any record of education to qualify them to perform moderate complexity assays. 2. Interview with the PoC supervisor at 12:30 pm confirmed that these four (4) individuals did not have documentation on site to verify a minimum of a high school diploma, required to perform moderate complexity testing. 3. The laboratory reports performing 552 whole blood HCG assays annually in the PoC area, using the Adexus instrument.

D6066

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:
Based on review of the testing personnel (TP) competency assessments presented for review during survey and interview with the Point of Care (PoC) supervisor, the laboratory failed to ensure that those TP performing Human Chorionic Gonadotropin (HCG) testing for pregnancy in the PoC area, had competency assessment since the last CLIA survey 11/28/2022. Findings include: 1. Of the TP reviewed for the PoC area, performing whole blood HCG testing for pregnancy, three (3) of four (4) TP were lacking competency assessment as assigned by the PoC supervisor. TP #1 Failure to complete 6 month competency assessment for HCG, was due 09/2024. TP #3 No competency assessment for HCG in 2022 or 2023 TP #4 No competency assessment for 2022 and failure to complete competency assessment for 2024, was due 09/2024. 2. Interview with the PoC supervisor at 1230 pm confirmed that there was no record of these three (3) TP completing the assigned competencies for HCG assay for pregnancy. 3. The laboratory reports performing 552 HCG assays for pregnancy annually.