Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D1085645	09/08/2020
Name of Provider or Supplier	**Street Address, City, State**	
Nw Pediatrics Integrative Medicine	11790 Sw Barnes Rd Bldg A Ste 140, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based upon review of records and discussion with staff during survey 09/08/2020, no written competency assessmment for testing personnel (TP) performing the Ray Biotech COVID IgG and IgM assays could be produced. Findings include: 1. When asked to review written competency assessments for the eight (8) TP listed on the CMS 209 form, none could be produced. 2. Staff confirmed during interview 09/08 /2020 at approximately 12:00 pm that no competency records for the COVID assays could be produced. 3. No written policy for assessing TP competency for the COVID assays could be produced during survey.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based upon review of procedures and discussion with staff, the Laboratory Director failed to ensure there was a current and signed off procedure for COVID testing in this laboratory. Findings include: 1. No written and approved procedure for the Ray Biotech COVID IgG and IgM assays could be produced during survey 09/08/2020.

D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based upon discussion with staff and review of the testing menu during survey 09/08 /2020, the Laboratory Director (LD) failed to full fill the LD's responsibilities. Findings include: 1. Upon review of the laboratory test menu during survey on 09/08 /2020, it was noted that the laboratory was offering COVID antibody testing. Staff was asked to provide the package insert for the two different COVID antibody tests. Upon review of the package insert, it was noted that this assay has not been reviewed by the FDA, making it a High Complexity assay. 2. This laboratory is a moderate complexity laboratory that is not approved for performing High Complexity testing. 3. The LD failed to ensure the COVID test he selected was appropriate for this laboratory.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based upon discussion with staff during survey and review of testing personnel records, the Laboratory Director (LD) failed to ensure testing personnel (TP) were qualified to perform High Complexity COVID testing. Findings include: 1. The eight (8) TP listed on the CMS 209 form provided during survey have not been qualified to perform High Complexity testing. 2. No evidence of validation of the Ray Biotech COVID IgG and IgM tests in use could be produced. 3. No written evidence of TP training for the Ray Biotech COVID IgG and IgM tests could be provided during survey 09/08/2020. 4. Staff confirmed during interview at approximately 12:00 pm that no written training documents existed.