Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D1085645	10/12/2021
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
D1002	REPORTING OF SARS-CoV-2 TEST RESULTS During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on review of COVID testing documents and interview with testing personnel (TP) and the Business manager for Integrative Pediatrics, the laboratory failed to report any of the COVID patient results to the County of Washington Public Health Department or the Oregon Health Authority. Findings include: 1. During survey 10/12 /2021, one of the TP and the business manager could not produce evidence of reporting the results of COVID testing to either the Washington County Public Health lab or the Oregon Health Authority. 2. Upon interview with the TP and Business manager on 10/12/2021 at approximately 1100 am, both personnel confirmed that the COVID patient test results (both positive and negative) were not being reported to any public health authority. 3. From 07/13/ 2021 through the date of survey 10/12/2021, 136 COVID tests were performed on patients using the Sofia SARS antigen test system. 127 of these tests were negative and nine (9) were positive. Testing was performed on 44 out of 89 days.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score,

	remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) for Hematology and discussion with one testing personnel (TP), the laboratory failed to follow up with corrective action on unacceptable white blood cell results. Findings include: 1. Upon review of hematology PT for the second event in 2021, one of five results for Lymphocyte % was scored unacceptable There was no written corrective action (CA) or review by the Laboratory Director (LD). 2. During an interview with one of the TP on 10/12/2021 at approximately 1230, she confirmed that there had been no CA or review by the LD.
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 on review of personnel competency records and discussion with one of the testing personnell (TP), the laboratory failed to perform competency assessment of TP performing laboratory testing. Findings include: 1. Upon review of the TP individual competency records, no written competency assessments for Hematology in 2021 could be produced for review during survey 10/12/2021. 2. During an interview with one TP during survey 10/12/2021 at approximately 1:00 pm, she confirmed that there were no written competency assessments for six (6) out of six (6) TP performing moderately complex Hematology testing. 3. The number of days moderately complex hematology patient testing was performed since the last survey 09/08/2020 through curreent survey is 35 days and a total of 45 tests. 3. Upon review of the TP individual competency records, no written training records for the Sofia COVID antigen test system could be produced for six (6) out of six (6) TP for 2021. 4. The number of days Sofia COVID antigen testing was performed since 07/13/2021 is 44 days and a total of 136 COVID tests..
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of Proficiency Testing records (PT) and discussion with one testing personnel (TP), the Laboratory Director (LD) failed to review PT performance for

	event #2 in 2021. Findings include: 1. For PT event #2, 2021, there was no written evidence of review or corrective action for the missed analyte Lymphocytes %.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the Proficiency Testing (PT) results available during survey and discussion with one testing personnel (TP), the Laboratory Director (LD) failed to ensure that an approved written corrective action (CA) plan for unacceptable performance was in place and followed. Findings include: 1. During survey 10/12 /2021, no approved CA plan for missed PT analytes could be produced. 2. An interview with one TP during survey 10/12/2021 at approximately 1:00 pm confirmed that there was no written and approved CA plan in place at this laboratory.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of personnel records and Procedure manuals, the Laboratory Director (LD) failed to ensure that policies and procedures are established and followed for testing personnel (TP) performing moderately complex tests. Finding include: 1. During survey 10/12/2021, no written competency assessments for TP performing moderately complex Hematology testing (CBC'S) could be produced for six (6) out of six (6) TP. 2. During survey 10/12/2021, no written policy or procedure for assessing TP competency in moderately complex Hematology testing could be produced. 3. During an interview 10/12/2021 at approximately 1:00 pm with one TP, she confirmed that no written policy or procedure for TP competency assessment was currently available.
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: Based on review of policies and procedures and discussion with one testing personnel (TP), the Laboratory Director (LD) failed to specify in writing which TP could perform moderately complex Hematology testing. Findings include: 1. No written designation of duties signed by the LD could be produced during survey 10/12/2021.