Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0904344	08/18/2021
Name of Provider or Supplier	**Street Address, City, State**	
Northwest Physicians Associates Pc	1012 Water Street Suite 8, Meadville, PA	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the American proficiency institute (API) proficiency testing (PT) records and interview with the technical consultant (TC) and Director of Operations, the laboratory director failed to sign the API PT attestation statements form 2019 and 2020. Findings Include: 1. On the day of survey, 08/18/2021, review of the API PT records revealed, the following event attestation statements were not signed by the laboratory director in 2019 and 2020: - 2019 API - Event #3 Chemistry. - 2019 API - Event #3 Hematology. - 2020 API - Event #1 Chemistry. 2. The TC and Director of Operations, confirmed the findings above on 08/18/2021 around 9:20 am.
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 the laboratory procedure manuals and interview with the technical consultant (TC) and Director of Operations, the laboratory failed to establish a competency assessment (CA) procedure to assess 1 of 1 clinical consultant (CC) and 1 of 1 TC for competency from 2019 to the day of survey. Findings include: 1. On the

	day of survey, 08/18/2021, the laboratory could not provide a written CA policy to assess the competency of 1 of 1 CC and 1 of 1 TC for competency in 2019, 2020 and 2021. 2. The TC and Director of Operations confirmed the findings above on 08/18 /2021 around 09:00 am.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of manual differential stain records and interview with the technical consultant (TC) and Director of Operations, the laboratory failed to test the manual differential stain (Quick III Stain) for reactivity each day of patient use for 128 out of 128 specimen examined from 08/18/2019 to 12/31/2020. Finding Include: 1. The Peripheral Blood examination Procedure states, "Quality Control: 1. Hematology stain Log must be checked daily". 2. On the day of survey, 08/18/2021, a review of the manual differential stain records revealed, the laboratory did not document stain reactivity each day of patient testing from 08/18/2019 to 12/31/2020. 3. In 2019 (08/18 /2019 to 12/31/2019), 41 manual differential specimens were examined. 4. In 2020, 87 manual differential specimens were examined. 5. The TC and the director of operations confirmed the findings above on 08/18/2021 around 10:20 am.
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 the American proficiency institute (API) proficiency testing (PT) records and interview with the technical consultant (TC) and Director of Operations, the Laboratory Director failed to ensure all PT reports received, were reviewed and corrective actions were taken for unsatisfactory PT performed in 2019. Findings include: 1. On the day of survey, 08/18/2021, review of the API PT records revealed, the laboratory did not documentation corrective actions taken for the following unsatisfactory PT events in 2019 and 2020: - 2019 Chemistry event #3: 60% for thyroid-stimulating hormone (TSH) and 80% for Triiodothyronine. 2. The TC and Director of Operations confirmed the findings above on 08/18/2021 around 09:15 am.
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d)

	(b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on lack of laboratory records and interview with the technical consultant (TC) and Director of Operations, the laboratory did not have the required records available during the inspection on 08/18/2021. Findings Include: 1. On the day of survey 08/18/2021, the laboratory could not provide the following records: - Monthly quality assessment (QA) records from August to December of 2019 and January to April of 2020. - Thermometer calibration records from 08/18/2019 to 09/04/2020. - Pipette calibration records from 08/18/2019 to 06/02/2020. - Centrifuge calibration records from 08/18/2019 to 08/08/2021. - Corrective action logs for the Tosoh AIA 900 from 05/2019 to 09/2020. - Calibration Verification performed on the Tosoh AIA 900 in 2020. 2. The TC and the Director of Operations confirmed the findings above on 08/18/2021 around 12:00 pm.