Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0889444	01/14/2020
Name of Provider or Supplier	**Street Address, City, State**	
North Park Medical Group	8363 Meadow Road, Dallas, TX	

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
D0000	The Clinic Manager and Testing Person-2 were at the entrance conference conducted 01/14/2020. The survey process was discussed. An opportunity for questions and comments was given. Exit conference was held with the Laboratory Director and Technical Supervisor on 01/14/2020. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas State Health and Human Services Commission, Health Facility Compliance Arlington Group.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of American Association of Bioanalysts (AAB) Proficiency Testing (PT) records and staff interview the laboratory failed to test immunohematology PT samples in the same manner as it tests patient specimens for 3 of 3 testing events in 2017 (Q-1, Q-2, Q-3) 3 of 3 testing events in 2018 (Q-1, Q-2, Q-3) and 3 of 3 (Q-1, Q-2, Q-3) testing events in 2019. Findings: 1. Review of AAB Attestation Statement revealed the following: "As published in the Federal Register February 28, 1972, Subpart H 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. [sic] The undersigned analyst attests that the samples were tested in the same manner as patient samples." Further review of the attestation statement revealed the following testing person-1 (TP-1) performed testing and the corresponding PT sample: Non Chemistry (D Rh typing) 2017: Q-1, Q-2, Q-3 Non Chemistry (D Rh typing) 2018: Q-1, Q-2, Q-3 Non Chemistry (D Rh typing) 2019: Q-1, Q-2, Q-3 2. During an interview on 01/14/2019 at 10:50 am, TP-1 stated that all testing persons that are present on the day of proficiency testing participate. She stated that every testing person performs PT in the lab on their own and all results are submitted to the laboratory director. She stated that the laboratory director reviews all results for discrepancies. When asked whose results were submitted to the PT company she stated that only her results were submitted. TP-1 was asked if all patient testing was performed in the same manner and she stated "no," confirming the above findings. The laboratory failed to test immunohematology PT samples in the same manner as it tested patient specimens.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of American Association of Bioanalysts (AAB) testing records, laboratory's CMS (Centers for Medicare & Medicaid Services) 209 form, and staff interview, the laboratory failed to ensure that patient samples were analyzed with the laboratory's regular patient workload by personnel who routinely perform testing in the laboratory for 3 of 3 events in 2017 (Q-1, Q-2, Q-3), 3 of 3 events in 2018 (Q-1, Q-2, Q-3), and 3 of 3 events in 2019 (Q-1, Q-2, Q-3). Findings: 1. Review of the AAB testing records revealed Testing Person-1 (TP-1) tested the following events: Non Chemistry (D Rh typing) 2017: Q-1, Q-2, Q-3 Non Chemistry (D Rh typing) 2018: Q-1, Q-2, Q-3 Non Chemistry (D Rh typing) 2019: Q-1, Q-2, Q-3 2. Review of the laboratory's CMS 209 form revealed five Testing Persons (TP-1, TP-2, TP-4, TP-7, TP-9) were listed as performing moderate complexity testing (immunohematology). Testing Person-1 (TP-1) Hire date: 02/12/2017 Testing Person-2 (TP-2) Hire date: 02 /13/2017 TP-2 has participated in testing patient specimens and had not participated in PT events. Testing Person-4 (TP-4) Hire date: 01/29/2018 TP-4 has participated in testing patient specimens and had not participated in PT events. Testing Person-7 (TP-7) Hire date: 10/24/2017 TP-7 has participated in testing patient specimens and had not participated in PT events. Testing Person-9 (TP-9) Hire date: 03/27/2017 TP-9 has participated in testing patient specimens and had not participated in PT events. 3. During an interview on 01/14/2019 at 10:50 am, TP-1 stated that all testing persons that are present on the day of proficiency testing participate. She stated that every testing person performs PT in the lab on their own and all results are submitted to the laboratory director. She stated that the laboratory director reviews all results for discrepancies. When asked whose results were submitted to the PT company she stated that only her results were submitted. Refer to D2006. The laboratory failed to ensure that patient samples were analyzed with the laboratory's regular patient workload by personnel who routinely perform testing.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation, review of the manufacturer's instructions, and staff interview, it was revealed that the laboratory failed to have documentation of the open date and/or the revised expiration date for the in-use Rh reagents. Findings: 1. Review of Immucor Anti-D (Monoclonal Blend) Gamma-clone instructions for use revealed: "PRECAUTIONS: For in vitro diagnostic use. Store at 1 to 10C when not in use ...Do not use beyond the expiration date ..." Review of Immucor Gamma-clone Control instructions for use revealed: "PRECAUTIONS: For in vitro diagnostic use. Store at 1 to 10C when not in use ...Do not use beyond the expiration date ..." 2. During a tour of the laboratory on 01/14/2020 at 9:15 am, the following Immucor in use reagents were observed on the counter with no open dates: 1 bottle of Anti-D (Monoclonal Blend) Gamma-clone, lot #506290, expiration date 03/19/2021, no open date 1 bottle of Gamma-clone Control, lot #350017, expiration date 09/10/2020, no open date 3. During an interview on 01/14/2020 at 11:20 am, testing person-2 confirmed the above findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy, personnel files and confirmed in interview the technical consultant failed to evaluate and document the performance for 4 of 9 Testing Persons (TP-2, TP-4, TP-7, TP-9) responsible for moderate complexity testing at least semiannually during the first year the individuals test patient specimens. Findings: 1. Review of the laboratory's "POLICIES AND PROCEDURES" policy revealed: "7) PERSONNEL ASSESMENT [sic] Existing staff will be reviewed on a yearly basis. New staff will be reviewed before the end of the probationary time (3 months). The review will include: A) Observation of patient preparation, specimen collection, handling and testing B) Recording and reporting of test results C) Conducting QC D) Observation of performance of instrument maintenance and function checks E) Assessment of performance by using analyzed samples or proficiency testing F) Competency with a new test or instrumentation if implemented." The policy failed to include semiannual competency assessments during the first year an individual tests patient specimens. 2. Review of personnel records revealed the following: TP-2: initial training was performed on 02/13/2017 and an annual competency on 02/19/2018 for Rh typing. There was no documentation of semiannual performance (due 08/2017). TP-4: initial training was performed on 02 /19/2018 and an annual competency on 02/18/2019 for Rh typing. There was no documentation of semiannual performance (due 08/2018). TP-7: initial training was performed on 02/19/2018 and an annual competency on 02/18/2019 for Rh typing.

	There was no documentation of semiannual performance (due 08/2018). TP-9: initial training was performed on 04/10/2017 and an annual competency on 04/10/2018 for Rh typing. There was no documentation of semiannual performance (due 10/2017). 3. During an interview on 01/14/2020 at 9:50 am, testing person-1 confirmed the laboratory failed to evaluate and document the performance for testing persons responsible for moderate complexity testing at least semiannually during the first year the individuals test patient specimens.