Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0423602	(X3) Date Survey Completed 02/13/2020
Name of Provider or Supplier Planned Parenthood Of Il - Near North Health Ctr	**Street Address, City, State** 1200 N Lasalle Blvd, Chicago, IL	

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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) 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 record review, the lack of documentation and an interview with the testing personnel (TP1); the laboratory failed to meet requirements under record retention for tests in the specialty of Microbiology. 1. The laboratory failed to meet the analytic test systems requirement to retain patient test records for at least 2 years. (See D3031).
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review, lack of documentation and an interview with the testing personnel (TP1); the laboratory failed to retain the patient test results for the

	Microbiology tests performed for at least 2 years. Findings include: 1. The laboratory's Potassium Oxide (KOH) and Wet mount procedures, patients' KOH and Wet mount Lab logs for the years of 2018 and 2019 and electronic medical records (EMR) were reviewed. 2. Ten (10) patients were selected for chart review of their KOH and Wet mount test results. 3. The patients' Lab logs and EMR records revealed the following: *The test logs failed to include a space to document the KOH and Wet Mount microscopic interpretation results. *The results of the microscopic interpretations were manually entered into the patients' EMR. *Ten (10) out of 10 patients' KOH and Wet mount results had been entered into the EMR. *The documentation of the original recorded microscopic results were not provided for the above patients. 4. The laboratory failed to ensure that the original KOH and Wet mount patient results were retained for 2 years after they had been transcribed into the EMR, during the years of 2018 and 2019. 5. The laboratory SOP failed to require the retention of patients' original written KOH and Wet mount results. 6. On a Recertification survey conducted on 02/13/2020 at 2:50 PM, the TP1 confirmed the above findings.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and an interview with the testing personnel (TP1); the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in transcribing patients' results for tests in the specialty of Microbiology. Findings include: 1. The laboratory's Potassium Oxide (KOH) and Wet mount procedures, patients' KOH and Wet mount Lab logs and electronic medical records (EMR) were reviewed. 2. The patients' Lab logs and EMR records revealed the following: *KOH and Wet mount results were transcribed manually into patients' EMR charts. *The original microscopic results of the patients were not retained. (See D3000 & D3031) *The laboratory failed to ensure test results were reliably and accurately transcribed into patients' EMR. 3. The laboratory manual failed to include a policy and procedure for monitoring and preventing transcription errors when clinicians manually enter patient results into the EMR. 4. On a Recertification survey conducted on 02/13/2020 at 2:50 PM, the TP1 confirmed the above findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 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. This CONDITION is not met as evidenced by: Based on record review, the Laboratory Personnel Report (CMS-209) and an interview with the testing personnel (TP1); the laboratory failed to employ individuals who meet the qualification requirements of 493.1423 for TP, affecting 4 out of 18 TP.

	Finding: 1. The laboratory failed to ensure laboratory personnel meet the qualification requirements for performing moderately complex testing in the subspecialty of ABO and RH Group . See D6065
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (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 This STANDARD is not met as evidenced by: Based on record review, the Laboratory Personnel Report (CMS-209) and an interview with the testing personnel (TP1); the laboratory failed to ensure laboratory employees meet the education qualification requirements for performing moderately complex testing prior to testing patients for 4 out of 18 TP. Findings: 1. The employee files and CMS-209 were reviewed. 2. The CMS 209 lists 18 TP (TP1, TP2, TP3, TP4, TP5, TP6, through TP18) performing Rhesus factor (RH) testing in the laboratory. 3. The employee files revealed the following: *The diploma of TP5 did not indicate what city, county, district or state from which it had been issued; *The diploma of TP14 had not been signed; *TP5 and TP15 failed to provided their high school transcripts as confirmation of graduation; *TP15 and TP18 failed to have their foreign education credentials evaluated for United States equivalency. 4. The laboratory failed to ensure TP5, TP14, TP15, and TP18 met the education requirement for performing RH factor testing, prior to testing patients. 5. On a Recertification survey conducted on 02/13/2020 at 2:50 PM, the TP1 confirmed the above findings.