| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 36D2070429 | 07/07/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Northeast Ohio Women's Center | 2127 State Road, Cuyahoga Falls, OH | |

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 |
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| **D2016** | SUCCESSFUL PARTICIPATION<br>CFR(s): 493.803(a)(b)(c)<br><br>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.<br><br>This CONDITION is not met as evidenced by:<br>Based on record reviews and an interview with the Administrator, the laboratory failed to successfully participate in a proficiency testing (PT) program for the non-waived Rh testing performed under the specialty of immunohematology. This deficient practice had the potential to affect 4000 patients tested under the specialty of immunohematology from 04/07/2021 to 07/07/2021. Findings Include: 1. Review of 2021 API PT documents revealed no 1st event testing records. 2. The inspector requested the 2021 API 1st event testing records from the Administrator. 3. The Administrator confirmed the laboratory failed to submit Rh PT results for the 2021 1st event testing which resulted in a subsequent unsuccessful analyte performance. The |

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| | administrator was unable to provide the requested documents on the date of inspection. The interview occurred 07/07/2021 at 10:55 AM. Rh: rhesus factor |
| **D5407** | PROCEDURE MANUAL<br>CFR(s): 493.1251(d)<br><br>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.<br><br>This STANDARD is not met as evidenced by:<br>Based on record reviews and an interview with the Administrator, the Laboratory Director (LD) failed to ensure policies and procedures were approved, signed and dated before use. This deficient practice had the potential to affect 4000 patients tested under the specialty of immunohematology from 04/07/2021 to 07/07/2021. Findings Include: 1. Review of the laboratory's policy and procedures provided on the date of the inspection revealed no LD approval signature and date. 2. The inspector requested policies and procedures approved, signed and dated by the LD from the Administrator. 3. The Administrator confirmed all policies and procedures were not approved, signed and dated by the LD before use. The interview occurred 07/07/2021 at 12:20 PM. |
| **D5891** | POSTANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1299(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and an interview with the Administrator, the laboratory failed to establish and follow written policies and procedures and document all assessment activities of the ongoing mechanism to monitor, assess, and correct problems identified in the post analytic systems. This deficient practice had the potential to affect 4000 patients tested under the specialty of immunohematology from 04/07/2021 to 07/07/2021. Findings Include: 1. Review of the laboratory's policy and procedure manual titled "P&P" provided on the date of the inspection found no instructions for postanalytic systems quality assessment. 2. The inspector requested the policy and procedure including documentation for all postanalytic systems quality assessment from the Administrator. 3. The Administrator confirmed the laboratory did not have an established policy or procedure for postanalytic systems quality assessment, no postanalytic quality assessment was performed, and was unable to provide the requested documents. The interview occurred 07/07/2021 at 11:40 AM. |
| **D6016** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(i)<br><br>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)(i) Ensure that the proficiency testing samples are tested as |

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| | required under Subpart H of this part;<br><br>This STANDARD is not met as evidenced by:<br>Based on record reviews and an interview with the Administrator, the Laboratory Director failed to ensure 2021 API 1st event proficiency testing (PT) activities were conducted as required under subpart H of this part. This deficient practice had the potential to affect 4000 patients tested under the specialty of immunohematology from 04/07/2021 to 07/07/2021. Findings Include: 1. Review of the laboratory's policy and procedure manual titled "P&P" provided on the date of the inspection found no instructions for PT. 2. Review of 2021 API core chemistry PT documents revealed no 2021 API 1st event testing records. 3. The inspector requested the 2021 API 1st event testing records for Rh from the Administrator. 4. The Administrator confirmed the laboratory failed to submit 2021 API 1st event testing for Rh which resulted in a subsequent unsuccessful analyte performance. The interview occurred 07/07/2021 at 10:55 AM. Rh: rhesus factor |
| **D6032** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(14)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record reviews and an interview with the Administrator, the Laboratory Director (LD) failed to specify the duties and responsibilities of each person listed on the Form CMS 209. This deficient practice had the potential to affect 4000 patients tested under the specialty of immunohematology from 04/07/2021 to 07/07/2021. Findings include: 1. Review of the Form CMS 209 found one individual, (the LD), listed as the Technical Consultant and five individuals listed as Testing Personnel. 2. Review of policies and procedures provided on the date of inspection failed to find evidence of the duties and responsibilities for the Technical Consultant and each Testing Personnel in writing by the LD. 3. The inspector requested the approved, signed and dated duties and responsibilities for the Technical Consultant and Testing Personnel from the Administrator. The Administrator confirmed the LD failed to specify in writing the duties of all personnel listed on the Form CMS 209 and was unable to provide the requested document. The interview occurred 07/07/2021 at 12: 20 PM. |
| **D6049** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)(iii)<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, |

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| | proficiency testing results, and preventive maintenance records.<br><br>This STANDARD is not met as evidenced by:<br>Based on record reviews and an interview with the Administrator, the Technical Consultant (TC) failed to include the review of intermediate test results or worksheets, quality control (QC) records and preventive maintenance records in the evaluation of the competency of Testing Personnel (TP) #1, TP#2, TP#3, TP#4 and TP#5. This deficient practice had the potential to affect 4000 patients tested under the specialty of immunohematology from 04/07/2021 to 07/07/2021. Findings Include: 1. Review of the laboratory's policy and procedure manual titled "P&P" provided on the date of the inspection found no instructions for competency assessments of TP. 2. Review of the laboratory's Form CMS 209, signed by the Laboratory Director on 07/06/2021, revealed five individuals indicated as TP. 3. The inspector requested the laboratory's 2021 competency assessment records for TP#1, TP#2, TP#3, TP#4 and TP#5 that included the review of intermediate test results or worksheets,QC records and preventive maintenance records from the Administrator. The Administrator was unable to provide the requested documents on the date of inspection. The interview occurred 07/07/2021 at 10:30 AM. |
| **D6050** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)(iv)<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.<br><br>This STANDARD is not met as evidenced by:<br>Based on record reviews and an interview with the Administrator, the Technical Consultant (TC) failed to include direct observation of performance of instrument maintenance and function checks in the evaluation of the competency of Testing Personnel (TP) #1, TP#2, TP#3, TP#4 and TP#5. This deficient practice had the potential to affect 4000 patients tested under the specialty of immunohematology from 04/07/2021 to 07/07/2021. Findings Include: 1. Review of the laboratory's policy and procedure manual titled "P&P" provided on the date of the inspection found no instructions for competency assessments of TP. 2. Review of the laboratory's Form CMS 209, signed by the Laboratory Director on 07/06/2021, revealed five individuals indicated as TP. 3. The inspector requested the laboratory's 2021 competency assessment records for TP#1, TP#2, TP#3, TP#4 and TP#5 that included direct observation of performance of instrument maintenance and function checks from the Administrator. The Administrator was unable to provide the requested documents on the date of inspection. The interview occurred 07/07/2021 at 10:30 AM. |
| **D6051** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)(v)<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.<br><br>This STANDARD is not met as evidenced by: |

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| | Based on record reviews and an interview with the Administrator, the Technical Consultant (TC) failed to include the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples in the evaluation of the competency of Testing Personnel (TP) #1, TP#2, TP#3, TP#4 and TP#5. This deficient practice had the potential to affect 4000 patients tested under the specialty of immunohematology from 04/07/2021 to 07/07 /2021. Findings Include: 1. Review of the laboratory's policy and procedure manual titled "P&P" provided on the date of the inspection found no instructions for competency assessments of TP. 2. Review of the laboratory's Form CMS 209, signed by the Laboratory Director on 07/06/2021, revealed five individuals indicated as TP. 3. The inspector requested the laboratory's 2021 competency assessment records for TP#1, TP#2, TP#3, TP#4 and TP#5 that included the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples from the Administrator. The Administrator was unable to provide the requested documents on the date of inspection. The interview occurred 07/07/2021 at 10:30 AM. |
| **D6052** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)(vi)<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.<br><br>This STANDARD is not met as evidenced by:<br>Based on record reviews and an interview with the Administrator, the Technical Consultant (TC) failed to include the assessment of problem solving skills in the evaluation of the competency of Testing Personnel (TP) #1, TP#2, TP#3, TP#4 and TP#5. This deficient practice had the potential to affect 4000 patients tested under the specialty of immunohematology from 04/07/2021 to 07/07/2021. Findings Include: 1. Review of the laboratory's policy and procedure manual titled "P&P" provided on the date of the inspection found no instructions for competency assessments of TP. 2. Review of the laboratory's Form CMS 209, signed by the Laboratory Director on 07 /06/2021, revealed five individuals indicated as TP. 3. The inspector requested the laboratory's 2021 competency assessment records for TP#1, TP#2, TP#3, TP#4 and TP#5 that included the assessment of problem solving skills from the Administrator. The Administrator was unable to provide the requested documents on the date of inspection. The interview occurred 07/07/2021 at 10:30 AM. |
| **D6063** | LABORATORY TESTING PERSONNEL<br>CFR(s): 493.1421<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on record reviews and an interview with the Administrator, the laboratory failed to ensure the individuals who performed moderate complexity testing met the qualification requirements of 493.1423 to perform the functions specified in 493.1425 |

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| | for the testing procedures performed. Findings Include: 1. The laboratory failed to ensure Testing Personnel (TP) met the education requirements, as specified in subpart M for moderate complexity testing procedures performed. (Refer to D6065) |
| **D6065** | TESTING PERSONNEL QUALIFICATIONS<br>CFR(s): 493.1423(b)(1)(2)(3)(4)(i)<br><br>(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<br><br>This STANDARD is not met as evidenced by:<br>Based on document reviews and an interview with the Administrator, the Laboratory Director failed to ensure prior to testing patients' specimens, Testing Personnel (TP) had the appropriate education to perform all test operations reliably to provide and report accurate results. This deficient practice had the potential to affect 4000 patients tested under the specialty of immunohematology from 04/07/2021 to 07/07/2021. Findings Include: 1. Review of the laboratory's Form CMS 209, approved, signed and dated on 07/06/2021 by the Laboratory Director revealed five TP. 2. The inspector requested education documents for all TP listed on the Form CMS 209 from the Administrator on 06/21/2021. Education documents were received for TP#3, TP#4 and TP#5. The inspector again requested education documents for TP#1 and TP#2 07 /06/2021 via email, 07/07/2021 during the inspection, and 07/13/2021 via email. The Administrator confirmed the laboratory did not have education documentation available for TP#1 and TP#2 and was unable to provide the requested documentation on the date or within seven days of the inspection. The interview occurred 07/07/2021 at 1:00 PM. |