| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number**<br><br>45D2293928 | **(X3) Date Survey Completed**<br><br>10/29/2024 |
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| **Name of Provider or Supplier**<br><br>Nhci Of Hillsboro, Inc Dba Hill Regional Hospital | **Street Address, City, State**<br><br>101 Circle Drive # 400, Hillsboro, 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** |
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| **D0000** | The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended. Standard level deficiencies were cited. |
| **D2007** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>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<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's policy and procedure, proficiency testing records, pre-survey paperwork, and interview the laboratory failed to ensure 10 of 12 testing personnel participated in proficiency testing (PT). Findings follow. A. Review of the laboratory's policy and procedure titled Proficiency Testing, effective 12/28/2023, under Policy stated "D. Surveys should be performed on a rotating basis among all testing personnel..." B. Review of the American Proficiency Institute (API) PT records from the 1st, 2nd, and 3rd events of 2024 showed they were all performed by testing personnel #1 and 2. C. Review of the presurvey paperwork titled CMS Form 209 showed there were 12 testing personnel for blood gases. D. Interview with the Technical Consultant (as listed on the CMS Form 209) on October 29, 2024 at 1115 hours in the conference room confirmed the findings. |
| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)<br><br>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. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's quality control (QC) records, pre-survey paperwork, analyzer log, and interview, the laboratory failed to retain the control package inserts for the Nova Biomedical STAT Profile Prime Auto QC Cartridge CCS lots in use for eight out of 10 months reviewed. Findings follow. A. Prior Nova Biomedical STAT Profile Prime Auto QC Cartridge CCS control package inserts were requested on October 29, 2024 at 1200 hours but not provided. B. Review of the pre-survey paperwork titled Annual Test Volume & Proficiency Testing Programs Worksheet showed patient testing began 12/28/2023 (elapsed time to survey was 10 months 1 day). C. Review of the instrument activities log showed the last cartridge lot was installed on 09/10/2024 (elapsed time since inception was 8 months 13 days). D. Interview with testing personnel #1 (as listed on the CMS Form 209) on October 29, 2024 at 1200 hours in the conference room stated they did not keep prior package inserts, only the current lot in use. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of verification of performance specifications records, pre-survey paperwork, and interview, the laboratory failed to verify the performance specifications for accuracy, precision, reportable range, and normal reference range for pH, partial pressure of Carbon Dioxide (pCO2), and partial pressure of Oxygen (pO2) performed on the Nova Biomedical STAT Profile Prime CCS for 10 of 10 months reviewed. Findings follow. A. Review of the verification of performance specifications for the Nova Biomedical STAT Profile Prime CCS, 10/19/2021, occurred under the last laboratory. Verification of performance specifications for the current laboratory was requested on October 29, 2024 at 1315 hours but not provided. B. Review of the pre-survey paperwork titled Annual Test Volume & Proficiency Testing Programs Worksheet showed patient testing began 12/28/2023 (elapsed time to survey was 10 months 1 day). C. Interview with the Technical Consultant (as listed on the CMS Form 209) on October 29, 2024 at 1315 hours stated the verification of performance specifications for precision, accuracy, reportable range, and normal reference range was not repeated when the analyzer was moved out of the main laboratory into the new laboratory. D. Review of the presurvey paperwork titled CMS Form 116 showed an annual test volume of 2712. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and |

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| | identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory test reports, pre-survey paperwork, and interview, the laboratory failed to include the name and address of the laboratory for 10 of 10 test reports reviewed in 2024. Findings follow. A. Review of 10 patients test reports did not have the name and address of the laboratory on the test report: Patient # Date of Service 1. 10084524 01/25/2024 2. 10088501 03/15/2024 3. 10090447 04/08/2024 4. 10090218 04/08/2024 5. 10092722 05/11/2024 6. 10096992 07/13/2024 7. 10099601 08/21/2024 8. 10101720 09/21/2024 9. 10102710 10/06/2024 10. 10102891 10/08/2024 B. Review of the presurvey paperwork titled CMS Form 116 showed an annual test volume of 2712. C. Interview with Technical Consultant (as listed on the CMS Form 209) on October 29, 2024 at 1145 hours in the conference room confirmed the findings. |
| **D6040** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(2)<br><br>The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of verification of performance specifications records, pre-survey paperwork, and interview, the technical consultant failed to ensure the verification of performance specifications for accuracy, precision, reportable range, and normal reference range for pH, partial pressure of Carbon Dioxide (pCO2), and partial pressure of Oxygen (pO2) was performed on the Nova Biomedical STAT Profile Prime CCS for 10 of 10 months reviewed (refer to D5421). |
| **D6046** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)<br><br>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's policy and procedure, pre-survey paperwork, competency evaluations, educational credentials, and interview, the technical consultant failed to perform the competency evaluations for 12 out of 12 testing personnel reviewed from 2024. Findings follow. A. Review of the laboratory's policy and procedure titled Training and Competency of Blood Gas Lab Staff, effective 12/28 /2023, under Policy stated, "B. Competency evaluations for testing personnel 1. Each Blood Gas Lab employee will be given a competency evaluation at Training, 6 |

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| | months from completion of training then annually thereafter. 2. The Medical Director or Technical Supervisor will assess the competency of each employee via a competency grid that will be completed by the employee and observed by either the General Supervisor or Technical Consultant, depending on the complexity of testing." The procedure was unclear, as the competency evaluations for moderate complexity testing should be performed by the Technical Consultant. B. Review of competency evaluations showed the following competency evaluations were performed by testing personnel: 1. Semi-annual competency evaluations for testing personnel #1 (as listed on the CMS Form 209) performed by testing personnel #2 on 07/03/2024; 2. Semi-annual competency evaluations for testing personnel #2 performed by testing personnel #1 on 07/03/2024; 3. Semi-annual competency evaluations for testing personnel #3 performed by testing personnel #2 on 07/03/2024; 4. Semi-annual competency evaluations for testing personnel #4 performed by testing personnel #2 on 06/12/2024; 5. Semi-annual competency evaluations for testing personnel #5 performed by testing personnel #2 on 02/22/2024 and 08/08/2024; 6. Semi-annual competency evaluations for testing personnel #6 performed by testing personnel #2 on 07/11/2024; 7. Semi-annual competency evaluations for testing personnel #7 performed by testing personnel #2 on 07/02/2024; 8. Semi-annual competency evaluations for testing personnel #8 performed by testing personnel #2 on 07/15/2024; 9. Semi-annual competency evaluations for testing personnel #9 performed by testing personnel #2 on 01/24/2024 and 07/18/2024; 10. Semi-annual competency evaluations for testing personnel #10 performed by testing personnel #2 on 03/07/2024; 11. Semi-annual competency evaluations for testing personnel #11 performed by testing personnel #2 on 04/25/2024 and 10/25/2024; 12. Semi-annual competency evaluations for testing personnel #12 performed by testing personnel #5 on 09/04/2024. C. Review of educational credentials revealed: 1. Testing personnel #1 had a high school diploma; 2. Testing personnel #2 had a GED; 3. Testing personnel #5 had a high school diploma. D. Interview with the Technical Consultant (as listed on the CMS Form 209) on October 29, 2024 at 1045 hours in the conference room confirmed competencies were performed by testing personnel who did not qualify as technical consultants. |