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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 10D1001608 | (X3) Date Survey Completed 09/18/2018 |
| Name of Provider or Supplier Nch Community Blood Center | Street Address, City, State 1100 Immokalee Rd, Naples, FL | |
| 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 | An unannounced complaint survey for CCR#2018013692 was conducted on 09/18/18 at NCH Community Blood Center, a clinical laboratory in Naples, Florida. The complaint contained one allegation that was substantiated with a deficiency. The laboratory was not compliance with Code of Federal Regulations (CFR), Part 493, requirements for clinical laboratories. The following is a description of the standard level deficiencies. |
| D1000 | <p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(c)</p> <p>Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others: (1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following: (i) Bilirubin; (ii) Glucose; (iii) Hemoglobin; (iv) Ketone; (v) Leukocytes; (vi) Nitrite; (vii) pH; (viii) Protein; (ix) Specific gravity; and (x) Urobilinogen. (2) Fecal occult blood; (3) Ovulation tests-visual color comparison tests for human luteinizing hormone; (4) Urine pregnancy tests - visual color comparison tests; (5) Erythrocyte sedimentation rate-non-automated; (6) Hemoglobin-copper sulfate-non-automated; (7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; (8) Spun microhematocrit; and (9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with laboratory personnel, this certificate of waiver laboratory has been performing non-waived testing. Findings include: During a complaint investigation on 09/18/18, the surveyor observed at 11:20 a.m. that there was a Bac T Alert instrument was in the laboratory. This instrument is used to perform quality control testing of platelets, a moderate complexity test. The laboratory</p> |

has a certificate of waiver, which prohibits them from doing moderately complexity testing. During an interview with the Quality Assurance Coordinator at 11:25 a.m. on 09/18/18, she confirmed that the laboratory had been doing bacteriology testing, but that when they were told that it was not a waived test, they ceased testing, and that starting 09/15/18 they sent specimens out to Creative Testing Solutions.