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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 31D0914105 | (X3) Date Survey Completed 12/18/2024 |
| Name of Provider or Supplier American Healthcare Services | Street Address, City, State 700 North Broad St, Elizabeth, NJ | |
| 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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| D3009 | <p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on an in-office review of the laboratory's requirements for a New Jersey State Clinical Laboratory License (NJCLL) under New Jersey Statutes Annotated: N.J.S.A. 45:9-42.28. License; necessity; categories, the laboratory failed to maintain NJCLL for calendar year 2024. A Surveyor for the Clinical Laboratory Improvement Services (CLIS) confirmed on 12/23/24 that the laboratory did not have a NJCLL license for 2024.</p> |
| D5401 | <p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Rhesus factor testing (Rh) and interview with the Testing Personnel (TP), the laboratory failed to have a procedure for Rh Tests performed with ALBAclone Anti-D blend Blood grouping reagent from 3/7/23 to the date of survey. The finding includes: 1. The laboratory did not have the Manufacturers Package Insert for ALBAclone Anti-D blend Blood grouping reagent. 2. The PM did not have a procedure for Rh testing using</p> |

ALBAclone Anti-D blend Blood grouping reagent 2. The TP confirmed on 12/18/24 at 1:00 pm that the aforementioned procedure was missing.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on surveyor review of Blood Grouping Reagent Anti-D blend ALBAclone Manufacturers Package Insert (MPI), laboratory Quality Control and Daily Laboratory Log (QCADLL) and interview with the Testing Personnel (TP), the laboratory failed to follow MPI for "Slide Technique" from 3/7/23 to the date of survey. The finding includes: 1. The MPI stated "Incubate the test for 5 minutes at 18-24c" 2. The TP stated they "incubate the slide on a heated view box" 3. The QCADLL recorded the view box temperature between 45-50C on each day of testing. 4. Approximately 1536 patients are run and reported annually. 5. The laboratory did not follow the MPI. 6. The TP confirmed on 12/18/24 at 1:30 pm that the MPI was not followed.