

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2227283	(X3) Date Survey Completed 12/09/2024
Name of Provider or Supplier Sollis Health Fl Inc	Street Address, City, State 324 Royal Palm Way Suite 100, Palm Beach, 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
D0000	A recertification survey was conducted on 11/21/2024 to 12/9/2024. Sollis Health Florida inc clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5787	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have patient test reports with specimen collection date and time, specimen received date and time, specimen type, and who performed the test for 10 of 10 patients, (#1, #2, #3, #4, #5, #6, #7, #8, #9, and #10). Findings included: Review of in house Patient Test Reports revealed the following: 1. Patient #1 had a respiratory pathogens DNA +RNA on 12/22/2023 at 2:16 PM. There was no written documentation of specimen collection date and time, specimen received date and time, specimen type, and/or who performed the test. 2. Patient #2 had a Troponin I performed on 11/17/2024 at 2:08 AM. There was no written documentation of specimen collection date and time, specimen received date and time, specimen type and/or who performed test. 3. Patient #3 had a D-Dimer performed on 11/12/2024 at 12:43 PM. There was no written documentation of specimen collection date and time, specimen received date and time, specimen type and/or who performed test. 4. Patient #4 had a D-Dimer performed on 11/11/2024 at 11:38 AM. There was no written documentation of specimen collection date and time, specimen received date and time, specimen type, and/or who performed test. 5. Patient</p>

#5 had a piccolo Metlac 12 on 11/15/2024 at 3:21 PM. There was no written documentation of specimen collection date and time, specimen received date and time, specimen type, and/or who performed test. 6. Patient #6 had a piccolo Metlac 12 on 11/09/2024 at 8:17 PM. There was no written documentation of specimen collection date and time, specimen received date and time, specimen type, and/or who performed test. 7. Patient #7 had a Gastrointestinal pathogens DNA +RNA on 10/14/2024 at 4:49 PM. There was no written documentation of specimen collection date and time, specimen received date and time, specimen type, and/or who performed the test. 8. Patient #8 had a Gastrointestinal pathogens DNA +RNA on 9/4/2024 at 2:11 AM. There was no written documentation of specimen collection date and time, specimen received date and time, specimen type, and/or who performed the test. 9. Patient #9 had a respiratory pathogens DNA +RNA on 9/10/2024 at 7:58 PM. There was no written documentation of specimen collection date and time, specimen received date and time, specimen type, and/or who performed the test. 10. Patient #10 had a respiratory pathogens DNA +RNA on 8/10/2024 at 9:56 PM. There was no written documentation of specimen collection date and time, specimen received date and time, specimen type, and/or who performed the test. Review of Test Reporting General Laboratory Policy & Procedure Manual signed by the laboratory director on 11/27/2024 read, "Instrument results may be printed directly from the analyzer and used as test reports if they contain complete patient information and reference ranges. If the patient information is lacking, apply a pre-printed sample label (if available), or hand-write patient identifying information to include: Who collected the sample, date and time. Who received the sample, date and time. Specimen type, where indicated." On 11/21/2024 at 4:53 PM, the Technical consultant confirmed the laboratory had not documented specimen collection dates and times, specimens received dates and times, specimen types and/or who performed the tests for 10 of 10 patient test reports.