

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2295253	(X3) Date Survey Completed 09/04/2024
Name of Provider or Supplier Sollis Health Fl, Inc	Street Address, City, State 1905 Clint Moore Road, Ste 303, Boca Raton, 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	An initial certification survey was conducted on September 4, 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 5 out of 5 patients, (#1 to #5). Findings included: Review of in house Patient Test Report revealed the following: 1. Patient #1 had a comprehensive metabolic panel performed on the piccolo on 2/12/2024 at 8:41 AM. There was no written documentation of specimen collection date and time, specimen received date and time, specimen type and who performed the test. 2. Patient #2 had a comprehensive metabolic panel performed on the piccolo on 2/13/2024 at 9:47 AM. There was no written documentation of specimen collection date and time, specimen received date and time, specimen type and who performed test. 3. Patient #3 had a complete blood count performed on the Poch100i on 2/13/2024 at 9:34 AM AM. There was no written documentation of specimen collection date and time, specimen received date and time, specimen type and who performed test. 4. Patient #4 had a complete blood count performed on the Poch100i on 3/22/2024 at 11:38 AM. There was no written documentation of specimen collection date and time,</p>

specimen received date and time, specimen type and who performed test. 5. Patient #5 had a comprehensive metabolic panel performed on the piccolo on 3/22/2024 at 11:39 AM. There was no written documentation of specimen collection date and time, specimen received date and time, specimen type and who performed test. Review of Test Reporting General Laboratory Policy & Procedure Manual signed by the laboratory director on 4/1/2024 revealed there was no policy for documentation of specimen collection date and time, specimen received date and time, specimen type and who performed test on test reports. On 9/4/2024 at 4:30 PM, the Technical consultant confirmed the laboratory had not documented specimen collection date and time, specimen received date and time, specimen type and who performed the tests for 5 out of 5 patients' test reports.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(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.

This STANDARD is not met as evidenced by:
Based on record review, and interview, the technical consultant failed to perform initial and 6 month competency assessments for 1 out of 6 Testing Personnel (TP) in 2024, (TP A). Findings Included: The Laboratory Personnel Report revealed employee A was TP A. Review of Testing Personnel Competency Assessments revealed no documentation of initial and 6 month competency assessment for TP A. Review of the General Policy and Procedure signed by the Laboratory Director on 4 /19/2024 revealed no policy for competency assessments and blank unfilled out competency assessment documents that read, initial, 6 month and annual. On 9/4/2024 at 4:41 PM, the Technical Consultant confirmed TP A's initial, and 6 month competency assessments were not performed in 2024.