

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2032923	<b>(X3) Date Survey Completed</b>  11/09/2023
<b>Name of Provider or Supplier</b>  Doctors Clinical Laboratory Services	<b>Street Address, City, State</b>  8280 Nw 27th St Ste 501, Doral, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey conducted from 10/25/2023 to 11/09/2023 found the DOCTORS CLINICAL LABORATORY SERVICES INC clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
<b>D2009</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, Testing Person (TP) failed to sign attestation for Proficiency Testing (PT) for 15 out of 15 modules reviewed from American Association of Bioanalysts (AAB)/Medical Laboratory Evaluation (MLE) PT in 2023. Findings included: -Review of AAB/MLE PT "GENERAL INSTRUCTIONS" on section "REPORTING RESULTS" stated: "Be sure to keep attestations statements printed from your online reporting form. The attestations must be signed for each analyte by the analyst performing the procedure and kept in files for inspection purposes." - Review of the following Modules of AAB/MLE PT records of 2023 revealed that the laboratory failed to have the analyst that performed each test to sign the attestation: Non-Chemistry M1: Culture ID, Urine; Parasitology; Coagulation; Parasitology. Chemistry M1: Fecal Occult Blood; Chemistry; Therapeutic Drug Monitoring; Tumors Markers; Urinalysis Module. Non-Chemistry M2: Parasitology; Miscellaneous Culture, Bacteriology. Chemistry M2: Endocrinology 1; Chemistry. During an interview on 10/26/2023 at 2:25 PM, General Supervisor confirmed that the laboratory failed to have TP sign the attestations forms for the modules listed above.</p>
<b>D3031</b>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p>

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.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to keep the instrument print out for 4 out of 6 patient test results reviewed in 2022 and 2023. Findings included: -Review of "POLICY RECORDS" revealed that "Doctor's Clinical Laboratory will maintain records on accordance with State and federal guidelines" and on "GUIDELINES" it stated: " Instrument print out must be stored for 2 years" Review of 6 final patient reports (P#1, P#2, P#3, P#4, P#5 and P#6) revealed that for patients P#2, P#3, P#4 and P#6, the laboratory failed to have the instruments print out for the following tests: P#2: Reported on 02/10/2022 for the following Chemistry tests performed on the Cobas C501 : Albumin, Alkaline Phosphatase (ALP), Alanine transaminase (ALT), Aspartate aminotransferase (AST), Total Bilirubin (TBIL), Blood Urea Nitrogen (BUN), Calcium (Ca), Cholesterol, Creatinine, Glucose, Total Protein (TP), Sodium, Potassium, Chloride, Triglycerides, Carbon Dioxide-CO<sub>2</sub>, Globulin. The laboratory could not provide the instrument print out for the tests results reported. P#3: Reported on 02/10/2023 for the following Chemistry tests performed on the Cobas C501 : Albumin, Alkaline Phosphatase (ALP), Alanine transaminase (ALT), Aspartate aminotransferase (AST), Total Bilirubin (TBIL), Blood Urea Nitrogen (BUN), Calcium (Ca), Cholesterol, Creatinine, Glucose, Total Protein (TP), Sodium, Potassium, Chloride, Triglycerides, Carbon Dioxide-CO<sub>2</sub>, Globulin. The laboratory could not provide the instrument print out for the tests results reported. PH#4: Reported on 02/24/2023 for the following Chemistry tests performed on the Cobas C501 : Albumin, Alkaline Phosphatase (ALP), Alanine transaminase (ALT), Aspartate aminotransferase (AST), Total Bilirubin (TBIL), Blood Urea Nitrogen (BUN), Calcium (Ca), Cholesterol, Creatinine, Glucose, Total Protein (TP), Sodium, Potassium, Chloride, Triglycerides, Carbon Dioxide-CO<sub>2</sub>, Globulin. The laboratory could not provide the instrument print out for the tests results reported. This patient also had reported test results for the Urinalysis performed on the Cobas U601, the laboratory could not provide the instrument print out for this test result. P#6: reported on 10/25/2023 reported test results for Urinalysis performed on the Cobas U601, the laboratory could not provide the instrument print out for this test result. During an interview on 10/26/2023 at 1:35 PM, the General Supervisor confirmed that the laboratory failed to have the instruments print out for the reported tests listed above.

**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 record review and interview, the laboratory failed to read urine cultures (UC) at 24 hours per their policy for 4 out of 6 patients reviewed for September and October of 2023. Findings included: Review of the policy "Urine Culture" revealed

that it stated: "Incubate overnight and read the following morning." Review of 6 patients final reports (P#10, P#11, P#12, P#13, P#14 and P#15) and worksheet reports for the cases of reference revealed that patients P#10, P#11, P#12, P#13 were not read at 24 hours period incubation as per following information: -P#10 was plated on 09/16/2023 and reported on 09/18/2023 with no growth, no reading done on the 24 hours. - P#11 was plated on 09/16/2023 and reported on 09/19/2023 with growth for Escherichia Coli, no reading done on the 24 hours. -P#12 was plated on 10/21/2023 and reported on 10/23/2023 with no growth, no reading done on the 24 hours. -P#13 was plated on 10/21/2023 and reported on 10/24/2023 with growth for Escherichia Coli, no reading done on the 24 hours. During an interview on 10/26/2023 at 10:30 AM, the Microbiology Supervisor confirmed that the laboratory failed to read the UC listed above at 24 hours as per their policy.