

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2032923	<b>(X3) Date Survey Completed</b>  08/27/2025
<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>	An announced CLIA recertification survey was conducted at DOCTORS CLINICAL LABORATORY SERVICES from August 26, 2025 to August 27, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
<b>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of package inserts and staff interview, the laboratory failed to properly label hematology quality control vials XN Check from Sysmex for the Sysmex Analyzer XN-1000 on 08/26/2025. Findings included: 1-During the laboratory tour on 08/26/2025 at 11:15 AM, the surveyor observed that the laboratory was using XN CHECK Cell Control with Lot number 51961101 for L1, 51961102 for level L2 and 51961103 for level L3, the vials had no open date and new expiration date. 2-Review of the XN-Check Cell Control user instructions revealed that used controls had an expiration date of seven days after first use. 3-During an interview on 08/26/2025 at 11:40 PM the laboratory manager confirmed that the vials were not labeled with the new expiration date. 49641 Based on observation, record review and staff interview, the laboratory failed to identify three glass jars used for immunology testing as per laboratory procedures for Human Herpesvirus (HSV), Helicobacter Pilory (H.P), and Antinuclear Antibody (ANA), with appropriate concentration, dates of preparation and date of expiration for August 26th of 2025 and August 27th of 2025. Findings included: 1- During a tour of the laboratory on 08/26/2025 at</p>

approximately 11:04 AM, observed three jars with liquid inside, labeled #1- QI WASH BUFFER HSV (1&2), #2- H. Pilory (30ml-720ml), #3- ANA (60ml-1000ml), respectively stored in the refrigerator approximately at 2 to 8 degrees Celsius. There was no labeling information for date of preparation, date of expiration of reagent as appropriate. 2- Review of the BIO-RAD HSV Type 1 & 2 IgG Enzyme Immunoassay (EIA) procedure stated in Section 4 REAGENTS Wash Concentrate Dilute in 1 liter of water or deionized water. Also, in section 6 "PRECAUTIONS FOR USERS for Invitro Diagnostic Use Users item 7 Wash Concentrate Cat No. 25190 not to be used beyond their expiration date." 3- Review of the procedure manuals for PILORI DETECT IgG # 25226 has instructions for REAGENT PREPARATION a diluent /wash preparation solution: " ...the final volume 750ML. Transfer the resulting solution to a Washer bottle and label it Working Diluent/Wash, store at 2-8 until the expiration date listed on the concentrate bottle." 4- Review of the BIO-RAD EIA ANA screening test procedure in Table 1. Wash Concentrate Preparation/Storage first bullet stated, "Requires dilution to prepare a Working Wash Solution." Second bullet stated, "Working Wash Solution is table for 14 days when stored at 2-8 C." Continued with "Warning for Users item 11. Do not use kit beyond its expiration date. The date is printed in kit boxes." 5- Review of the GENERAL LABORATORY PROCEDURE V.2 stated 1. All reagents, standards, controls, calibrators, stains, culture media and other critical supplies used in testing, etc. must be labeled with: date received, date opened, expiration date, safety hazard stickers (if applicable), storage requirements. Procedure also stated 3. Titer, strength or concentration must be identified when necessary. 6- Interview on 08/27/2025 at approximately 1:43 PM the TP4 confirmed that reagent jars for HSV, HP and ANA were not labeled as per procedure.

**D5417**

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

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:  
Based on observation and staff interview, the laboratory failed to ensure not to exceed their expiration dates for Hematology Immersion oil reagent used since 09-08-2024 through August 27, 2025. Findings included: 1- During a tour of the laboratory on 08/26/2025 at approximately 11:15 AM, observed three small bottles with dropper oil on the bench next to the microscope. 2- Review of the CMS-209 form submitted on 08-27-2025 and signed by the Laboratory Director on 08/01/2025, revealed that there were seven testing personnel (TP) in total, the two General Supervisors (TP1 and TP2) and other five personnel TP3, TP4, TP5, TP6 and TP7. 3-Review of the bottle labeling read low viscosity immersion oil Lot # 1293, Expiration Date 2024-09-08, with handwritten "6-8-22" blue Sharpe ink. 4- Review of the Hematology Procedure on Manual Differential Count, revealed in the SCAN PROCEDURE step 4. Using 100X oil objective, place a drop of oil on the slide and examine the smear for Platelet Morphology and count. Also, in step 5 stated "To perform the differential ..." and concluded with " ...you should use the 100X (oil) objective or 50X if available." 5- Sysmex XN Hematology Analyzers procedure signed by the laboratory director on 07/10/2024, states in table D. Differential Criteria: PLATELETS - SCAN the slide when Greater than 500,000 or less than 50,000, Immature Granulocytes (IG%) review slide when greater than (>) 5%. 6- Review of the Red Blood Cell (RBC) Morphology procedure stated in section 1. RBC EVALUTION " ... However, when quantitating

RBC morphology it should be performed using the 100X oil-immersion lens b. Using 100X evaluate abnormalities and inclusions ..." 7- Interview on 08/26/2025 at approximately 11:20 AM the GS/TP2 confirmed that the immersion oil in use was expired since 09-08-2024.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to perform maintenance for chemistry analyzer Cobas e 601 and Cobas c 501 as specified by the manufacturer for period reviewed January through December of 2024 and January through July of 2025. Findings included: 1- Review of the CMS-209 form submitted on 08-27-2025 and signed by the Laboratory Director on 08/01/2025, revealed that there were seven testing personnel (TP) in total, the two General Supervisors (TP1 and TP2) and other five personnel TP3, TP4, TP5, TP6 and TP7. 2- Review of maintenance records PN 3548-00-0113 for the Cobas e 601 SN 2486-23 revealed that the laboratory did not follow manufacturer instructions for the following events: a) every three months - to replace Pinch valve tubing from January 2024 through December 2024, and from January 2025 through March of 2025 b) every six months - to replace Pipettor seal from January 2024 through December 2024, and from January 2025 through July of 2025 3- Review of maintenance records PN 3547-00-0113 for COBAS c 501 SN 1146-13 revealed that the laboratory did not follow manufacturer instructions for the following events: a) every two months - to replace ISE measuring cartridges from January 2024 through December 2024, and from January 2025 through July of 2025. b) quarterly (#1) - to replace ISE pinch valve tubing from January 2024 through December 2024, and from January 2025 through July of 2025 c) quarterly (#2) - to replace ISE sipper tubing from January 2024 through December 2024, and from January 2025 through July of 2025, d) quarterly (#3) - to clean ultrasonic tubing from April 2024 through December 2024 e) every six months (#1) - to replace ISE reference cartridge from January 2024 through December 2024, and from January 2025 through July of 2025 f) every six months (#2) - to replace syringe seals, from January 2024 through December 2024 and from January 2025 through July of 2025. 4- Interview on 08/27/2025 at approximately 1:43 PM the TP4 admitted that maintenance was not recorded as per manufacturer frequency.