

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0505487	(X3) Date Survey Completed 01/13/2022
Name of Provider or Supplier Adc, Pllc, North Laboratory, The	Street Address, City, State 12221 North Mopac 4th Floor South, Austin, TX	
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 onsite survey conducted January 11, 2022 through January 13, 2022 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D3041	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6)</p> <p>Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting.</p> <p>This STANDARD is not met as evidenced by: Based on review of the histopathology case slides and interview, the laboratory failed to ensure histopathology slides were retained and accounted for in one of nine cases reviewed between 02/2015 - 12/2021. Findings follow. A. Review of one of nine cases showed Specimen S204947 from 2020 was missing the slide for the case. B. Interview with the histotech on January 12, 2022 at 1130 hours in the hall where slides were kept confirmed the slide was missing and acknowledged sometimes the pathologist would check out slides but not let the histotechs know who document the tracking of the slides.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p>

This STANDARD is not met as evidenced by:

I. Based on review of the manufacturer's instructions, the laboratory's policy and procedure, temperature charts, patient testing records, and interview, the laboratory failed to ensure the temperature was within manufacturer's requirements for four out of eight days of RPR (Rapid Plasma Reagin) testing using the BD Macro-Vue RPR Card Test for Syphilis testing in March 2021. Findings follow. A. Review of the BD Macro-Vue RPR Card Test package insert (0210745JAA(04), 2018-08), under Warnings and Precautions stated, "Controls and RPR card antigen suspension should be at room temperature (23 to 29 degrees Celsius when used)". B. Review of the laboratory's policy and procedure titled Macro Vue Rapid Plasma Reagin (RPR) Card Test revision May 27, 2020 under Warnings and Precautions stated, "Immediate use of a refrigerated antigen may result in decreased sensitivity of the test. Therefore, upon removal from the refrigerator, allow the antigen to warm to room temperature (23 to 29 degrees Celsius) before use." And under Procedure at Preliminary Preparations stated, "Controls, RPR Card antigen suspension and test specimens should be at room temperature (23 to 29 degrees Celsius) when used." C. Review of the temperature charts from 2021 showed the acceptable room temperature range was 17.0 - 27.0 degrees Celsius. Review of March 2021 showed the following testing dates with temperatures outside 23 to 29 degrees Celsius: 1. 03/05: 20.3 2. 03/09: 20.6 3. 03/16: 20.8 4. 03/25: 20.8 D. Review of patient testing records showed the following patients were tested as listed by sample ID: 1. 03/05: 9863177 2. 03/05: 9862983 3. 03/09: 9865727 4. 03/16: 9872564 5. 03/25: 9880559. E. Interview with testing personnel #7, listed on the CMS Form 209, on January 13, 2022 at 1130 hours in the laboratory confirmed the acceptable temperature range is outside the manufacturer's requirements and patient testing had been performed outside the acceptable range. 36342 II. Based on review of the ACL Elite Operator's manual, review of lot rollover records, surveyor observations, review of patient records, and interview with facility personnel, the laboratory failed to follow manufacturer instructions for changing the reference value used to calculate the international normalized ratio (INR) for 282 of 282 patient results tested between August 30, 2021 and January 11, 2022. The findings included: 1. Based on review of the ACL Elite Operator's manual, on page 4.30 under Setup and Utility, states the following: "PT NORMAL = Mean of the Normal Range (on the ACL Elite/Elite Pro this is called the Reference Value" and; "5. Select CALCULATION SETUP and the instrument will show in the right part of the screen the selection of the REFERENCE VALUE. This represents the Mean of the Normal Population value in SECONDS, which is used as the DENOMINATOR in the RATIO and INR CALCULATION." The manual's warning stated, "If the INR calculation is not properly setup, then erroneous patient results may be reported." 2. Based on review of lot rollover records from July 2021, the laboratory established a geometric mean of the normal patient range (MNPT) of 11.2 seconds for lot N0897673 of RecombiPlasTin 2G. 3. Based on surveyor observations at 16:17 hours on 1/11/2022 in the laboratory, the surveyor observed the reference value (MNPT) to be 11.50 seconds in the ACL Elite instrument software. 4. Based on review of patient records, the new lot of RecombiPlasTin 2G(N0897673) had been in use for patient testing since August 30, 2021. In total, 282 patient results were reported with the MNPT/Reference value from the previous lot (11.5 seconds). 5. In an interview at 16:17 hours on 1/11/2022 in the laboratory, the General Section Supervisor confirmed the Reference Value in the instrument software was not the reference value the laboratory had established in July 2021 and the value was not accurate for the current lot of RecombiPlasTin 2G reagent.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the manufacturer's instructions, the laboratory's policy and procedures, quality control (QC) records, LIS query, and interview, the laboratory failed to ensure a negative control was performed when they ran QC on the BD Affirm VPIII Microbial Identification Test used to test the presence or absence of Gardnerella vaginalis, Trichomonas vaginalis, and Candida species for 24 of 24 months reviewed in 2020 and 2021. Findings follow. A. Review of the BD Affirm VPIII Microbial Identification Test (version 670160JAA(04), 2019-06) Instructions for Use, under Quality Control stated "Quality Control requirements must be performed in accordance with applicable local, state, and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. It is recommended that the user refer to pertinent CLSI guidance and CLIA regulations for appropriate Quality Control practices." B. Review of the laboratory's policy and procedure titled Affirm VPIII Microbial Identification Test revised 12/01/2015 under Quality Control at Tri-Valent Swab stated, "the Tri-Valent swab serves as an external control and is performed once weekly and when a new lot or shipment is opened." The negative external control was not included in the policy. C. Review of QC records from Jan 2020 - Dec 2021 showed only the positive external control was run weekly. D. Interview with testing personnel #15, listed on the CMS Form 209, on January 12, 2022 at 1620 hours in the laboratory confirmed no negative swab was tested for external QC. Interview with Technical Supervisor #3, listed on the CMS Form 209, on January 13, 2022 at 0915 hours in her office confirmed only the positive control had ever been tested for external QC on the BD Affirm. E. LIS query of the annual patient testing volume was 332 for 2021.