Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0916278	02/11/2026
Name of Provider or Supplier	**Street Address, City, State**	
Amarillo Physicians Clinic	1215 Coulter, Suite 100, Amarillo, 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	A validation survey was performed on February 10-11, 2026 with standard level deficiencies cited.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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. In addition, retain the following: This STANDARD is not met as evidenced by: Based on review of laboratory records and confirmed in interview with the laboratory manager, the laboratory failed to maintain testing personnel (TP) records for at least two years for two of two TP. Findings included: 1. On 02/10/26 at 9:30 am, the laboratory manager confirmed the laboratory performed the following: a. CBC (Complete Blood Count) testing on the Sysmex XN-1000i b. Peripheral blood smears for manual differential testing by laboratory personnel. c. Urine Sediment examination d. Vaginal Wet Prep e. KOH examination 2. Review of the 2025 Hematology First Event PT attestation record dated 03/05/25 revealed the following: a. Testing person #4 (TP #4) - performed the Vaginal Wet Prep and KOH examination challenges (PT sample VA-01 and VKP-01) and Blood Cell ID (Educational) challenges (PT samples ECI-01, ECI-02, ECI-03, ECI-04, ECI-05) b. Testing person #5 (TP #5) performed the Hematology challenges (PT samples XE-01, EX-02, XE-03, XE-04, XE-05) 3. Review of 2025 TP records revealed no evidence of training records or competency assessments for TP#4 and TP#5. a. TP #4 -02/04/25 date of hire; 03/26/2025 last day of employment b. TP #5 - 09/05/2019 date of hire; 08/26/2025 last day of employment 4. In an interview on 2/10/26 at 2:15 pm, the laboratory manager stated TP records could not be located. Word Key: ID - Identification KOH - Potassium Hydroxide PT - Proficiency Test

D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's written procedure manual, record review, and confirmed in an interview with the laboratory manager, the laboratory failed to follow their own competency assessment procedure for one of one testing person (TP). Findings included: 1.The Laboratory Personnel Report (Form CMS-209) signed by the laboratory director on 2/11/26, listed two technical consultants. 2. A review of the laboratory's written procedure manual titled "LABORATORY PROCEDURE MANUAL", under the technical consultant job description, stated, "8. Evaluating competency." 3. Record review of one annual competency assessment revealed testing person #3, not the technical consultant, performed the annual competency assessment for testing person #1 (TP#1). 4. In an interview on 2/10/26 at 2:10 pm, the laboratory manager confirmed the findings above. II. Based on review of the laboratory's procedure manual, laboratory records, and confirmed in an interview with the laboratory manager, the laboratory failed to follow a hematology calculation verification procedure for one of one year. Findings included: 1.On 02/10/26 at 9:30 am, the laboratory manager confirmed the laboratory performed CBC (Complete Blood Count) testing on the Sysmex XN-1000i. 2. Review of the laboratory's written procedure manual titled "LABORATORY PROCEDURE MANUAL", under "SUBJECT: QUALITY CONTROL PROCEDURE", section "CALCULATION VERIFICATION" stated, "The parameters HCT, MCH, and MCHC are obtained from the XN 1000 instrument by calculation. The calculation of these parameters on the XN 1000 must be verified twice a year." 3. Review of quality control records from January 2025 through December 2025 revealed no evidence of a calculation verification every six months performed by the laboratory. 4. In an Interview on 2/10 /26 at 1:25 pm, the laboratory manager confirmed the findings above. Word Key: HCT - Hematocrit MCH - Mean Corpuscular Hemoglobin MCHC - Mean Corpuscular Hemoglobin Concentration III. Based on review of the laboratory's written procedure manual, patient test reports, and confirmed in interview with the laboratory manager and testing person #2 (TP #2), the laboratory failed to follow its own hematology procedure for nine of 16 patients. Findings included: 1.On 02/10/26 at 9:30 am, the laboratory manager confirmed the laboratory performed CBC (Complete Blood Count) testing on the Sysmex XN-1000i and also performed manual differential testing. 2. Review of the laboratory's written procedure manual titled "LABORATORY PROCEDURE MANUAL", under "SUBJECT: CBC REVIEW PROCEDURE", stated the following: a. "ATYPICAL LYMPHO" - "Perform a manual differential. Report out manual differential" b. "BLASTS/ABN LYMPHO?" - "Perform a manual differential. If immature WBCs are seen, send smear out. If no immature cells are seen, report out manual Differential". c. "PLT ABN DISTRIBUTION" - "Perform a peripheral smear and review platelets. Check for platelet clumps. Comment: "Platelet clumps seen" or "No platelet clumps seen"" d. "RBC AGGLUTINATION" - "Perform a peripheral smear. If rouleaux is seen, prewarm and repeat CBC" e. "TURBIDITY/HGB INTERF?"- "Check plasma for turbidity. If present report comments: "Lipemia present, Hgb results may be affected". 3. Review of patient reports revealed the laboratory failed to follow its procedure for 9

	of 16 patients as follows: a. ATYPICAL LYMPHO FLAG Patient ID: 1275752 - Reported on 12/04/25 - no manual differential performed Patient ID: 1280619 - Reported on 12/29/25 - no manual differential performed Patient ID: 1280653 - Reported on 12/29/25 - no manual differential performed b. BLASTS/ABN LYMPHO FLAG Patient ID: 1274806 - Reported on 12/02/25 - no manual differential performed Patient ID: 1276616 - Reported on 12/08/25 - no manual differential performed Patient ID: 1277211 - Reported on 12/10/25 - no manual differential performed c. PLT ABN DISTRIBUTION FLAG Patient ID: 1281168 - Reported on 12/30/25 - comment documented was "OCC large plts". This comment was not an acceptable comment associated with this flag. d. RBC AGGLUTINATION FLAG Patient ID: 1281040 - Reported on 12/30/25 - comment documented "Some RBC agglutination seen". No evidence of the prewarm and repeat of the CBC. e. TURBIDITY/HGB INTERF? FLAG Patient ID: 1281040 - Reported on 12/30/25 - comment documented "Noted" Patient ID: 1279655 - Reported on 12/22/25 - comment documented "Noted" 4. In an interview on 2/11/26 at 9:40 am, TP #2 confirmed the laboratory failed to follow its written procedure for flagged specimens. TP#2 stated the laboratory performed peripheral blood smears not manual differentials as required. Word Key: ABN - Abnormal HGB - Hemoglobin INTERF - Interference LYMPHO - Lymphocyte PLT - Platelet RBC - Red Blood Cells WBC - White Blood Cells
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure, review of patient test reports, and interview with testing personnel #2, the laboratory failed to have a procedure in place to define: +1, +2, +3, light, rare bacteria when reporting bacteria in the Wet Prep test from October 2025 to December 2025 as evidenced by: 1. In review of the laboratory's procedure, "Vaginal Wet Prep Procedure," stated under reporting results, "Clue Cells ... Trichomonas ... Yeast.." "Report each of the above as either presents or absent. There is also a line for reporting anything that is especially unusual i.e. large number of WBCs or RBCS, but it is not necessary to report anything in that space."

	The laboratory did not have in their procedure the definition of +1, +2, +3, light, rare, when reporting bacteria in the Wet Prep test. 2. In the review of the laboratory's patients from October 2025 to December 2025, the following patients were reported with bacteria seen in the wet prep test. a. 9/5/2025 patient ID # 684420 was reported as +2 bacteria. b. 9/17/2025 patient ID #143060 was reported as +1 bacteria. c. 9/19 /2025 patient ID # 225901 was reported as light bacteria. d. 9/23.2025 patient ID #757640 was reported as +1 bacteria. e. 9/30/2025 patient ID #1260582 was reported as +2 bacteria. f. 10/20/2025 patient ID #754000 was reported as rare bacteria g. 11/28 /2025 patient ID #735680 was reported as +3 bacteria h. 11/28/2025 patient ID #7560 was reported as +3 bacteria 3. In interview on 2/10/2026 at 1416 with testing personnel #2 confirmed that they had no procedure with specific defiinitions of bacteria reporting.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (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. This STANDARD is not met as evidenced by: Based on observation and confirmed in interview with the laboratory manager and testing person #2 (TP #2), the laboratory failed to label containers with the identity, expiration date, and lot number of contents for three of three Coplin jars. Findings included: 1. On 02/10/26 at 11:30 am, the laboratory manager confirmed the laboratory performed peripheral blood smears for manual differential testing. 2. Direct observation on 2/10/26 at 2:40 pm revealed three unlabeled Coplin jars filled with unknown reagents. 3. In an interview on 2/10/26 at 2:45 pm, TP #2 confirmed the unlabeled Coplin jars stored the AstralDiagnostics Quick III stain set (Fixative Solution, Solution I, and Solution II) used for manual staining of peripheral blood smears. TP#2 confirmed the laboratory failed to label containers with the identity, expiration date, and lot number of contents.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of laboratory records and confirmed in an interview with the laboratory manager, the laboratory failed to ensure patient test reports included the address of the laboratory location for two of two patient reports. Findings included: 1.

	On 02/10/26 at 9:30 am, the laboratory manager confirmed the laboratory performed the following: a. CBC (Complete Blood Count) testing on the Sysmex XN-1000i b. Routine Chemistry testing on the Abbott Alinity analyzer. 2. Review of the laboratory's CLIA certificate listed the laboratory's address as "7561 Outlook Dr." 3. Review of two patient reports revealed the laboratory's address did not match the address on the CLIA certificate. a. Patient# 628850 (Chemistry testing)- Report date 1 /5/26 listed the laboratory's address as "1215 Coulter, Suite 100". b. Patient #9304 (CBC testing) - Report date 1/23/26 listed the laboratory's address as "1215 Coulter, Suite 100". 4. In an interview on 2/10/26 at 12:20 pm, the laboratory manager confirmed the patient reports did not include the correct laboratory address.