Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0665369	05/06/2026
Name of Provider or Supplier	**Street Address, City, State**	
Clinics Of North Texas	501 Midwestern Parkway E, Wichita Falls, 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 announced validation survey of the laboratory was completed on 05/06/2026. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. Standard level deficiencies were cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS-209, review of the laboratory's policy, review of the laboratory's personnel records, and confirmed in interview, the laboratory failed to assess competency for one of two technical consultants involved in non-waived Chemistry, Hematology, and Microbiology testing in 2026. Findings include: 1. Review of the laboratory's submitted Form CMS-209 determined the laboratory had two technical consultants involved in Chemistry, Hematology, and Microbiology testing: technical consultant-1 (TC-1) and technical consultant-2 (TC-2). 2. Review of the laboratory's policy titled "POLICY: Laboratory Organizational Structure and Job Descriptions", approved by the laboratory director on 04/01/2002 stated: "B. Laboratory Director ...9. The Director ensures there is a sufficient number of personnel with appropriate educational qualifications, documentation of training and experience, and adequate competency to meet the needs of the lab." 3. Review of the laboratory's personnel records determined the laboratory director failed to assess competency for one of two technical consultants (TC-2) involved in Chemistry, Hematology, and Microbiology testing in 2026: a. Date evaluation period: 03/06/2026 Person doing evaluation: TC-1 Person being evaluated: TC-2 4. Technical consultant-1 (as listed on the CMS-209 form) confirmed the

	findings during an interview on 05/05/2026 at 1157 hours in the office. Key: CMS - Centers for Medicare and Medicaid Services
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, specimen labels and "LogSheets", and staff interview, the laboratory failed to ensure the collection time was documented on two of five Wet Mount specimens' labels delivered to the laboratory in January 2026. Findings included: 1. Review of the laboratory's Wet Mount procedure (policy number Lab-418.2, last reviewed December 2025) revealed: "SPECIMEN COLLECTION: ... Keep specimen at room temperature and deliver to the lab within 15 minutes of collection. (Trichomonas is only viable for one hour after collection)" 2. In an interview on 05/05/2026 at 1550 hours in the laboratory testing person number two (as indicated on submitted form CMS 209) indicated that the time of collection is electronically documented on the specimen label. 3. Review of laboratory's specimen labels on the Specimen LogSheet revealed two of five wet mount specimens delivered to the laboratory in January 2026 did not have the electronic documentation of collection time, making it unclear whether they met the delivery cutoff of 15 minutes. These were: Patient ID: 4748091 Date: 01/13/2026 Delivered to the laboratory at: 1143 hours Patient ID: 6523377 Date: 01/19/2026 Delivered to the laboratory at: 1503 hours 4. In an interview on 05/05/2026 at 1555 hours in the laboratory testing person number one (as indicated on submitted form CMS 209) confirmed the findings.
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 surveyor's observations, review of manufacturer instructions and staff interview, the laboratory failed to label one of one Innovance D-Dimer reagent in use with open/amended expiration date. Findings included: 1. Surveyor's observations on 05/06/2026 at 0935 hours in the laboratory revealed one in use Innovance D-Dimer Reagent bottle (Lot:568854; unopened expiration date: 2026-10-09) stored in the refrigerator without an open/amended expiration date, making it unclear when it was reconstituted. 2. Review of manufacturer instructions for the "Siemens Healthineers Innovance D-Dimer" (document 11531375_en Rev. 12 - USA only, 2024-11)

	revealed: "REAGENT Stability 2-8C (Degrees Celsius): reconstituted, 4 weeks" 3. In an interview on 05/06/2026 at 0935 hours in the laboratory, testing person number five (as indicated on submitted form CMS 209) confirmed the findings.
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: D5429 Based on review of the manufacturer operator's guide, review of the laboratory's Atellica CI Chemistry analyzer maintenance records, and confirmed in interview, the laboratory failed to ensure maintenance was documented at manufacturer required intervals for 15 of 22 events from December 2025 to February 2026. Findings include: 1. Review of the manufacturer operator's manual titled "Atellica CL Analyzer Operator's Guide", 11597559 Rev. 02 2023-06 stated: "Weekly system-defined activities The operator manually inspects the lamp coolant level and refills if appropriate. The operator manually cleans the exterior of the reagent probe. 2. Review of the laboratory's Atellica CI maintenance records determined the laboratory failed to ensure maintenance was performed at manufacturer required intervals for 15 of 22 events from December 2025 to February 2026: Weekly required maintenance: Checking the CH Lamp Coolant: Dates performed: a. 12/07/2025 b. 12 /22/2025 - 15 days c. 12/28/2025 - 6 days d. 01/05/2026 - 8 days e. 01/11/2026 - 6 days f. 01/19/2026 - 8 days g. 01/26/2026 - 7 days h. 02/02/2026 - 7 days i. 02/08 /2026 - 6 days j. 02/16/2026 - 8 days k. 02/22/2026 - 6 days Cleaning Exterior of Reagent Probe: Dates performed: a. 12/07/2026: not documented b. 12/14/2025 c. 12 /22/2025 - 8 days d. 12/28/2026 - 6 days e. 01/05/2026 - 8 days f. 01/11/2026 - 6 days g. 01/18/2026 - 7 days h. 01/26/2026 - 8 days i. 02/08/2026 - 13 days j. 02/15/2026 - 7 days k. 02/22/2026 - 7 days 3. Technical consultant-1 (as listed on the CMS-209 form) confirmed the findings in an interview on 05/05/2026 at 1622 hours in the office. Key: CMS - Centers for Medicare and Medicaid Services
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a) (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of manufacturer instructions and training documents, laboratory's policies, calibration logs, patient test logs and staff interviews, the laboratory failed to

	adhere to the manufacturer requirements for calibration curve 14-day stability for one of thirty-nine calibration curve studies performed in 2025 on the Polymedco OC-Auto Sensor io iFOB occult blood analyzer. Findings included: 1. Review of Polymedco instructions "OC-Auto SENSOR io iFOB TEST" (document 52798-00, 07/20/21) revealed: "OCIOL Latex Reagent for OC-Auto SENSOR io Stable until expiration then when stored unopened at 2 to 8C (Degrees Celsius). Open Vial Stability: 7 days when stored at 25C. Calibration stable for 1 week when latex reagent is stored at 25C. (Left on board analyzer)" 2. Review of Polymedco training document "OC-Auto Sensor io iFOB Training Checklist" (document PN 80854-00/SOP 0524 Rev.00, Attachment K, Revision date 07/19/2021) revealed: "Calibration ... Calibration curve is stable for 14 days when latex reagent is refrigerated at the end of the day" 3. Review of laboratory Policy number 422.5, "PROCEDURE: OC - Auto Sensor io" revealed: "OCIOL Latex Reagent: ... The latex reagent is stable for 2 weeks (14 days) if stored at 2 to 8C or for only 7 days if stored at 25C (left on board analyzer)." And, "OC-Auto Sensor io Calibration Kit ... 13. New calibration curve must be created under the following conditions: a. When lot of latex reagent is changed b. When the value of the positive control is not within the indicated range ... c. When open latex reagent is left on board for more than 7 days" The OC-Auto Sensor io Calibration Kit policy did not address the requirement for new calibration curves every 14 days as per manufacturer requirements due to 14 days refrigerated OCIOL Latex reagent stability. 4. Review of laboratory's "OC Sensor IO Calibration" logs from 2025 revealed the laboratory performed calibration at least every two weeks except for one missing calibration in June 2025. As indicated below: Calibration performed: 05/29/2025 Next calibration due: 06/12/2025 Next calibration performed: 6/23/2025 Number of elapsed days post required calibration: 11 There was no documentation available to verify when new lots or new bottles of OCIOL Latex reagent were opened or placed in use. The laboratory did not document lot numbers or expiration dates of reagents in use. 5. Review of patient test logs revealed the following patient samples were tested without required calibration: Sample: Tested: 1784641 06/13/2025 1780515 06/16/2025 1785214 06/16/2025 1785317 06/17/2025 1785546 06/18/2025 1782067 06/19/2025 1782475 06/19/2025 1783916 06/19/2025 1786250 06/19/2025 1786497 06/19/2025 1785904 06/20/2025 6. In an interview on 05/05/2026 at 1515 hours in the laboratory testing person number one (as indicated on submitted form CMS 209) confirmed the findings.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, and confirmed in interview, the laboratory failed to define staining characteristics for Wright-Giemsa stain for Hematology manual differential analysis in 2026. Findings include: 1. Review of the laboratory's policy titled "PROCEDURE: WBC Manual Differential", approved by the laboratory director on 03/26/1996, stated: "QUALITY CONTROL: A microscopic inspection of the first stained smear of each day should be evaluated for stain reactivity and debris." The surveyor requested documentation of intended stain reactivity for Wright-Giemsa stain for Hematology manual differential analysis. No documentation was provided. 2. Technical consultant-1 (as listed on the CMS-209 form) confirmed the findings in an

	interview on 05/06/2026 at 1008 hours in the office. Key: CMS - Centers for Medicare and Medicaid Services
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. This STANDARD is not met as evidenced by: A. Based on review of laboratory's policies/procedures, Prothrombin Time (PT) Innovin new lot establishment studies and staff interview, the laboratory failed to document verification of patients involved in the studies as "Normal" for two of two Innovin "Annual New Reagent/Control Studies" completed in 2024 and 2025. Findings included: 1. Review of laboratory's policy "Annual New Reagent/Control Studies" (policy number: 804.2, last reviewed 12/15/2025) revealed: "NORMAL PATIENT STUDY: A. To obtain the normal patient values, 20 patients will be drawn for this study. The following requirements must be met. ...4. The patients should NOT be on anticoagulants, aspirin, hormones, herbal supplements, vitamins, sinus or allergy medicine, or prescription medication." 2. Review of laboratory's Innovin new lot establishment studies for Lot 564665 (completed in December 2024) and Lot 564692 (completed in December 2025) revealed the studies did not contain documentation of verification that the patients involved in the Normal Patient studies followed the above eligibility requirement. 3. In an interview on 05/06/2026 at 0945 hours in the laboratory, testing person number one (as indicated on submitted form CMS 209), stated that the patients were asked verbally whether they were taking the above supplements/medications but there was no documentation of the patients' eligibility verification, confirming the findings. B. Based on review of laboratory's policies/procedures, Prothrombin Time (PT) Innovin new lot establishment studies and staff interview, the laboratory failed to document manual verification of INR (International Normalized Ratio) calculations for two of two Annual New Reagent /Control Studies completed in 2024 and 2025. Findings included: 1. Review of laboratory's policy "Annual New Reagent/Control Studies" (policy number: 804.2, last reviewed 12/15/2025) revealed: "1. Part of the Coagulation Annual Study is recalculating the INR based on the new PT mean and the new lot of Innovin's ISI (International Sensitivity Index) number." And, "Orchard verification a. Using an abnormal patient specimen or Level 3 control material order and run a test patient PT and APTT (Activated Partial Thromboplastin Time) b. Approve results in orchard and print out a report c. Calculate the INR being reported and check it against the orchard report" 2. Review of the Orchard Verification documentation revealed the laboratory used a computerized formula to verify INR calculation. There was no documentation of manual calculations to verify INR calculation's accuracy. 3. In an interview on 05 /06/2026 at 0945 hours in the laboratory, testing person number two (as indicated on submitted form CMS 209), stated that there was a computerized system that calculated the INR providing a complete range of INR values based on the new ISI, against which the Orchard Verification study INR was compared, but no manual calculations were performed. This confirmed the findings.
D5801	TEST REPORT CFR(s): 493.1291(a) (a) The laboratory must have an adequate manual or electronic system(s) in place to

	ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of manufacturer instructions, a sampling of laboratory's instrument printouts and corresponding patient reports, and staff interview, the laboratory failed to accurately report one of eleven analytes for its BIOFIRE FILMARRAY Gastrointestinal Panel Mid test implemented in November 2025. Findings included: 1. Review of manufacturer's instructions for "BIOFIRE FILMARRAY Gastrointestinal Panel Mid" (document BFR0002-7233-01, January 2025) revealed: "Clostridioides (Clostridium) difficile (toxin A/B) The BIOFIRE FILMARRAY GI Panel Mid contains a single multiplexed assay for the identification of toxigenic C. difficile which targets both the toxin A gene (tcdA) and the toxin B gene (tcdB)." 2. Review of manufacturer's instructions for Maine Molecular Quality Controls, Inc. "FilmArray GI Control Panel M238" (document M238 RUO Issued: 04142025 Rev. 5) revealed: "The FilmArray GI Control Panel M238 Is intended for use (as applicable) as an external positive and negative quality control for nucleic acid testing procedures to monitor the qualitative detection and identification of ... Clostridium difficile toxin A /B, Clostridioides (Clostridium) difficile (toxin A/B) ..." And, "Table 1: BIOFIRE GI Panel Result Summary Assay: Clostridium difficile toxin A/B M239 Call: Detected M240 Call: Not Detected Table 2: BIOFIRE GI Panel Mid Result Summary Assay: Clostridioides (Clostridium) difficile (toxin A/B) M239 Call: Detected M240 Call: Not Detected" 3. Review of a sampling of instrument printouts (sample number 1872753, tested 05/05/2026) revealed: Analyte: Clostridioides (Clostridium) difficile (toxin A/B) Result: Not Detected 4. Review of laboratory's final report for sample number 1872753 revealed: Analyte: Clostridium difficile toxin A/B Result: Not Detected The result on the final report referenced results for BIOFIRE GI Panel - detection of toxin A/B instead of the BIOFIRE GI Panel Mid results - detection of Clostridioides (Clostridium) difficile (toxin A/B) - as per instrument printout. 5. In an interview on 05/05/2026 at 1330 hours in the laboratory testing person number one (as indicated on submitted form CMS 209) confirmed the findings.
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's policies/procedures, patient test worksheets, patient

	final reports and staff interview the laboratory failed to ensure patient final reports contained results for all analytes tested for in a Wet Mount for five of five Wet Mount reports reviewed from January 2025. Findings included: 1. Review of the laboratory's Wet Mount procedure (policy number Lab-418.2, last reviewed December 2025) revealed: "3. Mainly four microbial forms are encountered when examining a wet mount. Grade as Rare, Few, Moderate and Many. a. Trichomonas vaginalis motile trophozoites. b. Budding yeast cells and pseudohyphae of yeast can be easily identified. c. Clue cells, which are completely covered by tiny, gram-variable rods and coccobacilli forming a bearding appearance of the edge of the cell is a sign of bacterial vaginosis. Gardnerella Vaginalis (sic) has been associated with this syndrome and a gram (sic) stain will confirm its presence. d. Many WBC's (white blood cells) in a wet preparation can be associated with other microbial infections such as Gonorrhea, which should be confirmed with a culture and/or gram (sic) stain (urethral) ... 4. In addition to the above-mentioned microscopic elements, the following are graded Rare to Many: a. Red blood cells b. Epithelial cells c. Bacteria d. Spermatozoa 5. If no elements are seen in the wet mount preparation, enter a comment on the report." The policy did not define quantification of each element per microscopic field to represent its semi-quantitative reporting of Rare, Few, Moderate and Many. 2. Review of laboratory's Wet Mount worksheets revealed the following analytes were addressed during microscopic examination: WBC (white blood cells) RBC (red blood cells) EPI (epithelial) CELLS BACTERIA (BACT) CLUE (cells) SPERM TRICH (Trichomonas) YEAST Testing personnel would circle the observations for each element as Rare, Few, Moderate or Many. The worksheet did not define quantification of each element per microscopic field to represent its semi-quantitative reporting of Rare, Few, Moderate and Many. 3. Review of final report for five of five patients tested in January 2026 revealed the following results: Patient: 4382628 Tested: 01/05/2026 Reported: WBC Moderate, RBC Few, EPI Moderate, BACT Moderate Report did not address examination for: CLUE, SPERM, TRICH, YEAST Patient: 8598460 Tested: 01/07/2026 Reported: WBC Few, RBC Many, EPI Few, BACT Few Report did not address examination for: CLUE, SPERM, TRICH, YEAST Patient: 4748091 Tested: 01/13/2026 Reported: WBC Few, RBC Many, EPI Moderate, BACT Many Report did not address examination for: CLUE, SPERM, TRICH, YEAST Patient: 0653377 Tested: 01/19/2026 Reported: WBC Many, EPI Many, CLUE Moderate, BACT Many, TRICH Moderate Report did not address examination for: RBC, SPERM, YEAST Patient: 8391720 Tested: 01/26/2026 Reported: WBC Few, EPI Many, BACT Moderate Report did not address examination for: RBC, CLUE, SPERM, TRICH, YEAST 4. In an interview on 05/05 /2026 at 1555 hours in the laboratory testing person number one (as indicated on submitted form CMS 209) confirmed the findings.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, patient sample labels, sample delivery/receipt logs, test worksheets, patient final reports and quality assurance records, the laboratory's quality assurance failed to ensure patient final reports accurately reflected collection, receipt and testing/result entry time for five of five

	Wet Mount samples tested in January 2026. Findings included: 1. Review of the laboratory's Wet Mount procedure (policy number Lab-418.2, last reviewed December 2025) revealed: "SPECIMEN COLLECTION: ... Keep specimen at room temperature and deliver to the lab within 15 minutes of collection. (Trichomonas is only viable for one hour after collection)" The policy did not address accurate specimen collection/receipt time verification/entry. 2. Comparative review of Wet Mount patient sample labels, sample delivery/receipt logs, test worksheets and final reports revealed the final reports did not accurately reflect times of collection, receipt and testing as follows: Patient: 4382628 Test date: 01/05/2026 Sample label collection time: 11:19:19 AM Sample log delivery time: 11:22 AM Sample log receipt time: 11: 28 AM Sample worksheet test time: Not documented Final report specimen collection time: 11:34 AM Final report specimen receipt time: 11:34 AM Final report test/result entry time: Not documented Patient: 8598460 Test date: 01/07/2026 Sample label collection time: 04:18:10 PM Sample log delivery time: 04:21 PM Sample log receipt time: 04:26 PM Sample worksheet test time: Not documented Final report specimen collection time: 16:35 (04:35 PM) Final report specimen receipt time: 16:35 (04:35 PM) Final report test/result entry time: Not documented Patient: 4748091 Test date: 01 /13/2026 Sample label collection time: Not documented Sample log delivery time: 11: 43 AM Sample log receipt time: 11:46 AM Sample worksheet test time: Not documented Final report specimen collection time: 12:18 PM Final report specimen receipt time: 12:18 PM Final report test/result entry time: Not documented Patient: 6523377 Test date: 01/19/2026 Sample label collection time: Not documented Sample log delivery time: 15:03 (03:03 PM) Sample log receipt time: 15:04 (03:04 PM) Sample worksheet test time: Not documented Final report specimen collection time: 15:20 (03:20 PM) Final report specimen receipt time: 15:20 (03:20 PM) Final report test/result entry time: Not documented Patient: 8391720 Test date: 01/26/2026 Sample label collection time: 11:49:50 AM Sample log delivery time: 11:54 AM Sample log receipt time: Not documented Sample worksheet test time: Not documented Final report specimen collection time: 12:27 PM Final report specimen receipt time: 12:27 PM Final report test/result entry time: Not documented 3. Review of laboratory's quality assurance (QA) records from January through March 2026 revealed the laboratory's QA did not identify or address issues where laboratory's Wet Mount final reports did not accurately reflect times of collection, receipt and testing. 4. In an interview on 05/05/2026 at 1555 hours in the laboratory testing person number one (as indicated on submitted form CMS 209) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services